

UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

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In Re: Bair Hugger Forced Air) File No. 15-MD-2666
Warming Devices Products) (JNE/FLN)
Liability Litigation)
) October 25, 2017
) Minneapolis, Minnesota
) Courtroom 12W
) 9:07 a.m.
)

BEFORE THE HONORABLE JOAN N. ERICKSEN
UNITED STATES DISTRICT COURT JUDGE

THE HONORABLE FRANKLIN L. NOEL
UNITED STATES MAGISTRATE JUDGE

THE HONORABLE WILLIAM H. LEARY
RAMSEY COUNTY DISTRICT COURT JUDGE

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P R O C E E D I N G S

(9:07 a.m.)

THE COURT: Please be seated. Mr. Sacchet, we cut you off yesterday. Did you have any last thoughts that you wanted to clear up?

MR. SACCHET: There is one thought I did want to clear up.

THE COURT: Yeah. I'd be happy to hear from you. If I had a heart and if I had feelings, I would have felt bad for cutting you off.

MR. SACCHET: Don't worry. I guess I should clarify your question, though, Your Honor. With respect to the time, are you just referring to Holford's motion or Borak's motion as well?

THE COURT: I think we're almost done with Holford.

MR. SACCHET: Yeah. I agree.

THE COURT: What I was wondering is if you had a couple of things you wanted to say about Borak, and I know that Borak is very dependent on Holford, and that comes through, of course, in your memo. So I don't anticipate that you have too much to say, and if you want a specific number of minutes, I can make up a number.

MR. SACCHET: I was hoping maybe to go 10 minutes on Borak.

1 THE COURT: All right.

2 MR. SACCHET: Unless that's extreme.

3 THE COURT: No. Do it.

4 MR. SACCHET: Okay. And I did have a housekeeping
5 matter. I have copies of the decs that we presented
6 yesterday that we would be happy to give the Court. I
7 conferred with my friends on the other side, and they have
8 copies as well.

9 THE COURT: No one is admitting to being your
10 friend.

11 MR. SACCHET: I would hope they would.

12 THE COURT: So, Mr. Blackwell, do you have a
13 similar dec?

14 MR. BLACKWELL: We do, Your Honor.

15 THE COURT: Okay. Would you mind just giving us
16 those a little bit later because we're over -- underwhelmed
17 with space up here.

18 MR. SACCHET: I understand. The only matter left
19 with respect to Mr. Albrecht and the under power calculation
20 that was brought up at the end of my presentation yesterday
21 and --

22 THE COURT: Albrecht?

23 MR. SACCHET: Mr. Albrecht opines on the same
24 matter that Professor Holford did with respect to the double
25 power calculation. I wanted to read a quick excerpt from

1 Mr. Albrechts' testimony. Mr. Albrecht's testimony has been
2 cited often and I think miscited as well, and when he was
3 asked specifically about what happens when you control for
4 both hypothetical confounders, does it actually in fact
5 reduce the odds ratio or make it disappear.

6 And yesterday I explained to the Court that when
7 you cut the population of the McGovern study in half from
8 approximately 2400 patients --

9 THE COURT: Down to 600, you don't have a
10 statistical significance.

11 MR. SACCHET: There's an issue of numbers, and
12 when Mr. Albrecht was asked this question: If you were to
13 analyze the data factor taking into consideration the
14 antibiotics and the Rivaroxaban and if that factor goes out,
15 do you still think there would, even with observational
16 data, it would show a difference between Bair Hugger and
17 HotDog.

18 And Mr. Albrecht responded, I don't know. There's
19 a period of time here which comes into play. There's
20 possibly not enough infections, infections to do a multi
21 varied analysis like that where it's properly powered. I'm
22 not so sure we'd be able to tease out the effect of multiple
23 factors at the same time with the data set that has, you
24 know, few infections like that over multiple cuts of
25 variables.

1 So that's Mr. Albrecht's testimony as to the
2 issues with controlling for two hypothetical confounders on
3 an extremely small duty set within an extremely reduced
4 infection risk ratio.

5 MAGISTRATE JUDGE NOEL: On that point, authors
6 reaffirming their conclusions in McGovern, is there some
7 place in your memo, I think there is, but I don't have it
8 clearly in mind, and if not, is there somewhere where you
9 can direct us to where each of the authors who were deposed
10 reaffirmed the conclusion of the study?

11 MR. SACCHET: I can.

12 THE COURT: And that conclusion being that there's
13 an association?

14 MR. SACCHET: I can. If you can give me a minute,
15 though, and this could take an unnecessary amount of time.

16 MAGISTRATE JUDGE NOEL: If you don't want to take
17 the time right now, if one of your colleagues can be looking
18 for that, and you can give it to us at some point before
19 you're done.

20 MR. SACCHET: I appreciate that. Okay.

21 THE COURT: Would it be in your memorandum in
22 support of Professor Holford?

23 MR. SACCHET: So I believe we cited it in two
24 memos. I believe I did direct citations in the opposition
25 to 3M's motion to exclude Samet with testimony from

1 Dr. McGovern saying that he stands by the 3.0 risk ratio not
2 only based on the published McGovern study, but also based
3 on the data that was collected after the study. That
4 statement is in our papers.

5 Also, in our Holford papers we cited deposition
6 testimony from both Dr. McGovern and Professor Nachtsheim to
7 the same effect, although I don't believe we included a
8 parenthetical citation stating the precise words of their
9 testimony, but I will look for that, and we will present it
10 to the Court in due time.

11 On to Dr. Borak, you are very correct, Your Honor,
12 that Borak's report in large part relies on Professor
13 Holford's analysis, so I will not be repeating that. What I
14 will do is identify the three ways in which Dr. Borak's
15 testimony differs from Professor Holford's, and I will go
16 through that very quickly.

17 The first is that with respect to Dr. Borak's
18 opinions regarding the relationship between SSI measures and
19 the outcome of interest in this litigation, deep joint
20 infection, he proffers additional testimony on that subject
21 matter, precisely identifying two particular SSI measures
22 that Professor Holford failed to identify. Those are
23 namely, one, the impact or potential impact of skin
24 preparation; and two, the potential impact of NSSA's nasal
25 screening, and he analyzes those in his report.

1 The first thing to bear mentioning again is that
2 Dr. Borak admitted on the record that he did in fact
3 conflate in his report SSI with DJI, and as I was saying
4 yesterday, they have different etiologies, and I won't
5 re-explain that for the Court again in light of the time,
6 but with respect to the two particular factors of interest
7 that he did analyze, the first was skin preparation.

8 And just as a quick background, some of the
9 patients in the McGovern -- in the Bair Hugger arm received
10 a solution called Povidone-iodine, and that changed in the
11 HotDog group where some patients received chlorhexidine, and
12 Dr. Borak speculates, and it's apparent in the record, that
13 that change, even though it deals with topical skin
14 preparation, could have impacted DJI.

15 And in this colloquy, he makes that clear, and I
16 won't reread it because it's here in the record, and we will
17 provide copies for the Court, but the notable statement is
18 at the end where he essentially says, to the extent that
19 this would have an impact on DJI, then it would be
20 considered a confounder, but he never concludes that skin
21 preparation is in fact a confounder.

22 MAGISTRATE JUDGE NOEL: Is there any studies post
23 McGovern like the one you were describing on the word I
24 can't pronounce.

25 MR. SACCHET: Rivaroxaban?

1 MAGISTRATE JUDGE NOEL: Yes. That's the one where
2 there was a post study that shows that it doesn't confound.
3 Is there any post McGovern study on either the skin
4 preparation or the antibiotic change or any of the other
5 alleged confounders, or is it just that -- the one I can't?

6 MR. SACCHET: Rivaroxaban. I'm not particularly
7 aware of studies with respect to skin preparation and MSSA
8 nasal screening that has concluded that there is a
9 relationship, and to be honest I think it would be a curious
10 conclusion because when I deposed Dr. McGovern and I asked
11 the question, Are you aware of any studies that would
12 evaluate this relationship, he was surprised that I would
13 even ask that question because skin preparation is a topical
14 on your skin. There is no relation to the joint.

15 The MSSA nasal screening is in the nose. It can
16 perhaps cleanse bacteria, but the biological plausibility is
17 questionable, and in light of that, I don't think the
18 authors have taken the step to conduct a true study to show
19 that it is not a confounder, but it's the opposite burden.
20 In order to show that it is a confounder, both the citations
21 in Dr. Holford and Dr. Borak's report show that there must
22 be literature showing a substantial difference between one
23 regimen and another, and based on that literature, you can
24 conclude that there is confounding.

25 You cannot conclude that there is confounding

1 based on an a priori assumption in the absence of evidence
2 that there is confounding. You need scientific proof to
3 make that determination.

4 MAGISTRATE JUDGE NOEL: But how is -- everybody
5 gets hoisted by their own by tar. Isn't that the point
6 they're making about your evidence on bacteria generally?
7 In other words, your point is, got to be some way to get
8 that bacteria in there. Common sense suggested if you're
9 sucking up dirt from the floor and blowing it up the other
10 end, maybe it's going to be a source of the bacteria that
11 gets into the joint.

12 But they keep saying you have no evidence of that.
13 You have no measured study showing increase in bacteria on
14 the agar plates or however else you can count bacteria. So
15 isn't that -- am I missing something?

16 MR. SACCHET: I'll address it two ways. First,
17 there are studies showing statistically significant
18 increases in bacteria as a result of the Bair Hugger, and
19 that is the Moretti study.

20 MAGISTRATE JUDGE NOEL: Okay. I'll have to look
21 at Moretti again because Moretti has come up, but Blackwell
22 comes back and yells at us that no, Moretti doesn't say
23 that.

24 MR. SACCHET: Review that. So I can tell you that
25 although there was a statistically significant increase in

1 bacteria as a result of the Bair Hugger, there were no deep
2 joint infections, but that's because there was 20 patients.
3 Again, you're not going to have statistically significant
4 increase in infection when your population is 20 persons.

5 So they want to come up here and argue that that
6 study doesn't matter because of that. In my view, it's
7 scientific sophistry. What it does show in its plain text
8 is that there's a statistically significant increase in
9 bacteria when the Bair Hugger is turned on, and that's fact.
10 My second response would be, well --

11 JUDGE LEARY: I'm going to get back to when you
12 make a comment like, in my opinion it's sophistry. I keep
13 on wanting to get back to the idea of, you have to
14 establish, plaintiffs have to establish, and the defendants
15 as well, for any proposition they're asserting with regard
16 to scientific principle that it's in the record, and the
17 flavor of comments within my opinion, it really doesn't
18 advance the ball.

19 MR. SACCHET: There is a document that we've put
20 in the record, Your Honor. It was cited in our response to
21 3M's motion to exclude Dr. Samet, Dr. Jarvis and
22 Dr. Stonnington in which 3M's corporate witness Mr. Al van
23 Duren explains that in order to have a properly powered
24 study, there would need to be more than a thousand patients,
25 and he determined that that was not a good study to conduct

1 because it would have been a bad career move.

2 JUDGE LEARY: So does he support your opinion that
3 the other topic that you're addressing was sophistry? I
4 mean, he makes that statement as a matter of principle, but
5 as applied to the statement you made, does he express any
6 opinion?

7 MR. SACCHET: He does not directly say that
8 Moretti was under powered with respect to deep joint
9 infection rates, but he does say you need at least a
10 thousand people or more.

11 JUDGE LEARY: I understand that.

12 THE COURT: So the question that keeps bothering
13 me, I may or may not be able to articulate it. In making a
14 distinction between DJI and SSI, the plaintiffs make the
15 what appear to be valid scientific points about the
16 differences, and yet in the theory of how Bair Hugger
17 increases DJI, you look at information about bacterial
18 counts on the surface of things, like agar plates or bubbles
19 or -- these are, you're counting things that are above the
20 surface, not down below.

21 And at several points, it seems that you're
22 arguing that nothing that happens on the surface, nothing
23 about SSI, has any relevance at all to the question of the
24 ability of any instrumentality that increases air flow or
25 bacteria in the air, that the SSI has no bearing whatsoever,

1 but I mean, if it an agar plate has some bearing, why
2 wouldn't an SSI have some bearing?

3 MR. SACCHET: So I hope I answer your question.

4 THE COURT: Just try it, without the preamble,
5 otherwise we run out of time.

6 MR. SACCHET: First, SSIs require hundreds of
7 bacteria, and deep joint infections require just a few, and
8 that's why there's a difference in, if you just got a small
9 inoculum of bacteria on an agar plate that you can capture
10 based on the bacteria that may land close to the surgical
11 wound that that increases the risk compared to a different
12 type of infection.

13 The second point is that with respect to
14 confounding, there has been no scientific literature to
15 suggest that surgical site infection interventions have a
16 substantial impact on deep joint infection rates, and part
17 of that inquiry is biological plausibility. So when we
18 discuss something like the anti thrombotic, which I think
19 goes back to Judge Noel's question a bit earlier about,
20 okay, well, you're talking about common sense here. You're
21 arguing about that, well, the Bair Hugger picks up bacteria
22 and then it could spit it out and put it on the wound. If
23 that makes sentence, then why doesn't it apply the same way
24 with respect to confounders?

25 Let's talk about an anti thrombotic. It is an

1 anticoagulant or a blood thinner that prevents
2 vasoconstriction. There's no relationship to the joint, and
3 Professor Holford even admitted in his deposition that
4 temporality is likely not even satisfied because Rivaroxaban
5 is generally administered post-operatively, when a deep
6 joint infection can occur during the operation.

7 So there's a caveat there with respect to the
8 common sense appeal of the chain of infection, which we
9 believe we have proven, versus speculation about whether
10 hypothetical confounders that have no relationship to a
11 joint in fact substantially increase deep joint infection
12 risks.

13 MAGISTRATE JUDGE NOEL: Let's go back to the
14 common sense point, which is -- so the surface preparation,
15 as I understand it, is just what you've put on the area that
16 you're going to cut into to disinfect it before you make the
17 cut.

18 MR. SACCHET: Precisely.

19 MAGISTRATE JUDGE NOEL: And if in fact you are
20 removing more bacteria with one preparation than another,
21 doesn't that ipso facto reduce the potential number of
22 bacteria that might fall into the deep incision once it's
23 made to cause the infection, or is that ipse dixit?

24 MR. SACCHET: Two points: One, there's been no
25 showing that there is a reduction between Povidone-iodine

1 and chlorhexidine with respect to that outcome; and two, our
2 theory of the case is, even if you've got an open wound, the
3 Bair Hugger could disrupt convection currents and create
4 thermal bodies by which bacteria could be redeposited in
5 that wound space.

6 So there is a mechanism of infection that is not
7 dependent on what's on the skin before or what's on that
8 area, you know, prior to this cut of the wound. It's what
9 happens once the wound is open and once the Bair Hugger is
10 turned on and whether as a result more bacteria and more
11 particles that otherwise would not be deposited on the
12 surgical site are in fact being deposited there.

13 THE COURT: So is it -- is the atmosphere
14 completely without any bacteria or particle bearing bacteria
15 in the absence of the Bair Hugger?

16 MR. SACCHET: That's a great question and this is
17 one of the reasons --

18 THE COURT: Why thank you. Got one.

19 MR. SACCHET: This is one of the reasons why
20 orthopedic cases are different than other types of cases.
21 Use of the Bair Hugger in orthopedic case is the primary
22 problem and why we have not brought cases that are non
23 orthopedic cases. In orthopedic procedures, there is
24 downward airflow for the express purpose of taking all of
25 the particles and bacteria that would otherwise exist in the

1 atmospheric area above the surgical wound and moving them
2 down in a way from the surgical site and through the exhaust
3 vents of the operating room.

4 In other types of surgery, there is not that
5 degree of protection. When you put the Bair Hugger in an
6 operating room environment that otherwise has this
7 protective effect created by uni directional air flow, the
8 CFD analysis that Ms. Conlin showed you yesterday with
9 respect to the turbulence that is created from the Bair
10 Hugger changes the whole dynamic.

11 The whole purpose of uni directional flow is to
12 reduce and eliminate the particles and bacteria that are in
13 the operating room environment for an orthopedic surgery
14 precisely because a single bacterium can cause a deep joint
15 infection.

16 THE COURT: So the same operation rooms are used
17 in multiple surgeries. You've got that downward airflow, so
18 they don't wheel people into a special operating room to do
19 orthopedic surgeries. So that alone -- I don't know that
20 they do.

21 MR. SACCHET: In some cases I think they do, Your
22 Honor.

23 THE COURT: Well, not always. I know orthopedic
24 surgery centers and trailers and whatnot. If there were no
25 HotDog, how would your argument for -- how would your

1 argument be different in the absence of a HotDog?

2 Would you still be saying that the Bair Hugger
3 manufacturer is liable for increased infections if the
4 evidence -- I know this whole colorectal thing, but as the
5 defendants are saying, we actually overall take the HotDog
6 totally out of it, overall if you're going to have your
7 knees or hips replaced, you're better off having a Bair
8 Hugger than nothing.

9 And so how would your argument -- do you still
10 have a case if your argument isn't HotDog is better than
11 Bair Hugger if your argument is, nothing is better than Bair
12 Hugger?

13 MR. SACCHET: Three responses. The first is that
14 there are many other products than the HotDog that have been
15 shown to have equivalent efficacy in terms of warming
16 patients.

17 THE COURT: Okay. So that would be similar to, it
18 doesn't have to be the HotDog, but something else. So
19 that's the comparison between Bair Hugger and some new and
20 improved something and other. Okay. So my question is,
21 what if we don't have any of this new and improved something
22 or other? What if it's Bair Hugger versus nothing?

23 MR. SACCHET: There is an intermediate
24 consideration which is, there are methods of warming that
25 don't involve conductive fabric or forced air warming that

1 have also shown to be effective in retaining normothermia
2 that have been used for centuries, not centuries but decades
3 prior to the introduction of forced air warming.

4 And third, we would dispute that the evidence
5 shows that in orthopedic cases that the use of forced air
6 warming is beneficial for reducing infections.

7 THE COURT: Forced air warming or any warming?

8 MR. SACCHET: There was -- any warming.

9 THE COURT: So your argument is, you're better off
10 with nothing than a Bair Hugger?

11 MR. SACCHET: In your hypothetical, without the
12 use of other products that are on the market that may or may
13 not be the HotDog, I would still revert to other means of
14 passive warming that do exist and have been used for a long
15 time.

16 If you're going to take all types of other warming
17 things off the table and just say in a vacuum there is the
18 Bair Hugger and there's no other way to warm a patient,
19 which would you do? In an orthopedic case, I would say
20 don't warm the patient, for infection, for purposes of
21 infection.

22 THE COURT: Okay. Because that helps me
23 understand whether you're saying the Bair Hugger shouldn't
24 be used at all, or now that we have other things, our
25 position is, yeah, use these other things instead.

1 MR. SACCHET: And there are a lot of other things.

2 THE COURT: Whether there are or aren't, the legal
3 point that you're making is that Bair Hugger is liable for
4 the incremental increase over these other things versus Bair
5 Hugger is liable for the incremental increase over nothing.

6 MR. SACCHET: What I would also say is, there are
7 other forced air warming devices that are not the Bair
8 Hugger.

9 THE COURT: What do the experts say about those?
10 Nothing.

11 MR. SACCHET: I may not be the precise person to
12 ask that question. One of the issues in the case is the
13 filtration of the Bair Hugger, and there are other forced
14 air warming products that have better filtration than the
15 Bair Hugger thereby ameliorating one of the two causal
16 mechanisms of infection.

17 THE COURT: Are there studies that show that
18 forced air warming system that has a HEPA filter creates
19 less infection than one that doesn't have a HEPA filter?
20 Where do we look in the record for some support for that
21 proposition?

22 MR. SACCHET: The documents that Ms. Conlin
23 proffered yesterday, which is the ECRI update, precisely --

24 THE COURT: The ECRI update doesn't say much. The
25 bulk of that update has to do with something else, and they

1 do have that line about it, but there's nothing in there
2 about any science.

3 So what study shows that a HEPA filter makes a
4 difference?

5 MR. SACCHET: Okay. Well, in terms of making a
6 difference, there's been numerous studies that have been
7 shown when you compare different types of filtration of the
8 Bair Hugger device how much bacteria can come out of the
9 device. So some of the first studies that were published on
10 the Bair Hugger, namely Albrecht 2009, Albrecht 2011, those
11 studies compared different types of Bair Hugger devices, the
12 505 and the 750, and determined that 3M reduced the
13 filtration of the Bair Hugger device from having a filter
14 that was in the 90 percent range to one that was in the
15 60 percent range and thereby emitted almost 40 percent of
16 particles.

17 THE COURT: Was there a corresponding 40 percent
18 increase in DJI?

19 MR. SACCHET: So there is not been a study that
20 has precisely linked HEPA filtration or other types of
21 filtration, to my knowledge, to deep joint infection. What
22 I will say is this, however: In the Al Van Duren study,
23 which was conducted I believe in 1992, the authors there
24 analyzed the Bair Hugger and found that there was an
25 increased amount of bacterial sedimentation on agar plates

1 from the product.

2 The authors there expressly concluded that to
3 reduce the risk of deep joint infection, it should be
4 quipped with a HEPA filter.

5 THE COURT: And then did they put a HEPA filter in
6 and test the difference?

7 MR. SACCHET: They never have used a HEPA filter.

8 THE COURT: I mean, how hard would it be to put an
9 agar plate out and run the Bair Hugger with or without a
10 HEPA filter? Has anybody done that?

11 MR. SACCHET: HEPA filters reduce 99.9 percent.

12 THE COURT: Has anybody done that? No.

13 MR. SACCHET: I don't believe so.

14 THE COURT: Okay. And if the problem is the
15 disturbance of the air flow wouldn't matter if you filtered
16 it, right?

17 MR. SACCHET: No. There can be bacteria on the
18 floor of the operating room, which as Ms. Conlin explained
19 yesterday is known to be the unsterile area of the operating
20 room in which uni directional flow pushes everything to the
21 ground.

22 THE COURT: We have that.

23 MR. SACCHET: So even if you have a Bair Hugger
24 that has a great filter, if it's releasing excess heat,
25 which is what the Bair Hugger does compared to other forced

1 air warming products, that creates the disruption that then
2 brings that sedimentation and bacteria from the floor back
3 to the surgical wound site, regardless of the filtration of
4 the device.

5 THE COURT: So the temperature matters?

6 MR. SACCHET: Yes. And namely, the amount of
7 excess heat that is released by the device, which in terms
8 of the 750, the current Bair Hugger that is on the market,
9 it is a marked increase from the prior models of the device.
10 That is one of the reasons that we allege that the
11 convection currents that are created are extremely strong,
12 and our CFD modeling shows the amount of turbulence that is
13 created in an otherwise sterile environment.

14 THE COURT: Using what temperature?

15 MR. SACCHET: That is released from the device?

16 THE COURT: Right.

17 MR. SACCHET: I'm going to hand that comment to my
18 colleague.

19 THE COURT: Your expert said 105. I'm just
20 wondering where he gets that.

21 MAGISTRATE JUDGE NOEL: 106.

22 THE COURT: 105 or 106.

23 MR. SACCHET: Where we get the precise temperature
24 reading?

25 THE COURT: Right.

1 MR. SACCHET: I apologize. I'm not qualified to
2 answer the question.

3 THE COURT: But the temperature matters is what
4 you are saying, and you are qualified to say that the
5 temperature makes a difference. You just said that that's
6 not the only problem, but the temperature matters.

7 MR. SACCHET: One study in particular, the Dasari
8 study, independent study, found that the thermal gradient
9 between use of the Bair Hugger around the surgical site
10 versus with the Bair Hugger off is also markedly different.

11 THE COURT: Okay.

12 JUDGE LEARY: I want to follow up to your answer
13 to one of Judge Ericksen's questions. Is it your position
14 with regard to prosthetic knee and hip surgeries that
15 actually it would be better for the patient in terms of
16 outcome not to be warmed? Is that what you're representing?

17 MR. SACCHET: That's a broad question in terms of
18 what the outcome is, Your Honor.

19 JUDGE LEARY: I just want to know, is that what
20 you're representing? And if so, if you're representing
21 that, is there anywhere in the record that would support
22 what you just said?

23 MR. SACCHET: If the outcome is deep joint
24 infection, I would say I would prefer -- I would prefer the
25 Bair Hugger should not be used.

1 JUDGE LEARY: I'm not talking about the Bair
2 Hugger, I'm talking about warming devices. Are you saying
3 that with regard to a prosthetic hip surgery or prosthetic
4 knee surgery that it's better not to warm the patient at
5 all?

6 MR. SACCHET: No.

7 JUDGE LEARY? You're not saying that?

8 MR. SACCHET: No.

9 THE COURT: So what's the point?

10 MAGISTRATE JUDGE NOEL: Just so I understand, I
11 thought what your answer was, if the question is whether
12 there's going to be a deep joint infection or not, you would
13 rather have nothing than the Bair Hugger, but Judge Leary's
14 question is broader than that saying, generally outcome
15 across the board of all prosthetic device surgeries, you're
16 not saying that you should never have anything?

17 MR. SACCHET: I interpreted Judge Leary's question
18 to not be exclusive of Bair Hugger versus nothing because he
19 mentioned other types of warming. So if other types of
20 warming are in play, they should be used, because they don't
21 increase the risk of infection as has been shown with the
22 Bair Hugger.

23 THE COURT: Can they decrease the risk of
24 infection? Never mind. All right. Go ahead.

25 MR. SACCHET: I'll try to finish up with

1 Dr. Borak. There are two other aspects of his testimony.
2 In his report, Dr. Borak contends that above and beyond all
3 other potential confounding factors, and I want to emphasize
4 that.

5 Above and beyond all potential other confounding
6 factors that a psychological phenomenon known as the
7 Hawthorne effect confounded the results of the McGovern
8 study. The Hawthorne effect occurs when there are
9 participants in a study who are being observed and thereby
10 modify their behavior thereby skewing the results of the
11 outcome of the study, because they're not in fact acting as
12 they normally would and instead changing their behaviors
13 that then --

14 THE COURT: The well-known effect.

15 MR. SACCHET: The well-known effect.

16 THE COURT: Get that for all the studies for
17 people washing their hands and they leave the bathroom.

18 MR. SACCHET: When we cross examined Dr. Borak on
19 this question, he readily admitted, as he had to, that he
20 had no idea if the patients knew that they were being
21 studied because the McGovern study is a retrospective study.
22 There was no Hawthorne effect, so my contention is, above
23 all and beyond all other confounders, if he's arguing that
24 that's the primary confounder, all the other ones fall with
25 it.

1 The last topic that Dr. Borak offers is his
2 general causation findings. Dr. Borak, unlike Dr. Samet,
3 did not review the totality of evidence. He critiqued and
4 attacked one study, as we know, the McGovern study. He
5 predicated his opinion that the Bair Hugger is not a
6 substantially contributing cause of infection based on that
7 analysis alone.

8 He admitted he was not qualified to consider the
9 mechanism of infection that is on page 30 of his deposition.
10 He admitted he did not evaluate the impact of convection
11 currents caused by the Bair Hugger and whether that
12 increases the risk of infection. He admitted he did not
13 evaluate the filtration issues that have come up today, in
14 his report. That is on page 103 of his deposition.

15 What he also admitted is that temporality is
16 readily satisfied, which is the first and only prerequisite
17 under the Bradford Hill criteria. He also admitted that if
18 you have an odds ratio of less than 2.0 that that can still
19 suggest or show causation.

20 He admitted that particle studies contribute to
21 coherence, and finally, he admitted that infectious microbes
22 being harbored in the Bair Hugger unit, it seems reasonable
23 to suggest that they can create the risk of infection.

24 Based on these admissions and Dr. Borak's failure
25 to consider multiple lines of evidence beyond the McGovern

1 study, he did not follow well accepted scientific methods as
2 an epidemiologist would do in considering the totality of
3 evidence in these mechanisms of infection to determine
4 whether the Bair Hugger does increase the risk of infection
5 and cause infection.

6 And for all these reasons, Dr. Borak should be
7 excluded, just as Dr. Holford.

8 MAGISTRATE JUDGE NOEL: Let me ask one last
9 question from my perspective. If the Court were somehow
10 able to conclude, and I understand there is no motion to
11 this effect, but if we were just to say McGovern is bad
12 science, McGovern goes out, none of your witness -- all of
13 your witnesses get to testify but they can't mention
14 McGovern, would you still have a case?

15 MR. SACCHET: Yes. And I'm going to compare it to
16 *Glastetter*.

17 MAGISTRATE JUDGE NOEL: I'm sorry?

18 MR. SACCHET: If you'll entertain, I could compare
19 this case to *Glastetter*. In *Glastetter*, first and foremost,
20 it was a pharmaceutical case. The plaintiffs there offered
21 a number of forms of evidence ranging from medical texts,
22 animal studies, internal documents and things of that
23 nature.

24 I do want to note, but I'm not emphasizing this,
25 that the Court expressly said you don't need epidemiologic

1 studies in order to show causation, but this was the wrinkle
2 in *Glastetter* that does not exist here. They had no
3 evidence to link the relationship between the
4 vasoconstrictive properties of parlodel with the chemical
5 that would result in increased stroke.

6 There was some surmise. There was ipse dixit to
7 suggest that. Here, we have established a chain of
8 infection that links it together, and we also have studies
9 that have odds risk ratios. The Darouiche study expressly
10 found that there is a 2.0 times increased risk for each
11 10 cubic feet -- not cubic feet -- cubic centimeters of CFUs
12 to deep joint infection.

13 That's what separates this case from *Glastetter*.
14 We have a mechanism infection, and the parties agree to all
15 of the intermediate steps.

16 THE COURT: Let me just ask. Let me go back on
17 the ultra clean theater business. You said that orthopedic
18 surgeries are -- so are all the plaintiffs here plaintiffs
19 who were operated on in one of these special ultra clean
20 theaters? Is that a significant factor?

21 I mean I think what you're telling me is that
22 orthopedic surgeries are conducted in a different operating
23 theater than an other surgery, and first of all, is that
24 somewhere in the record?

25 MR. SACCHET: It is in the record. There are

1 studies shown that ultra clean ventilation is used in
2 orthopedic surgeries, the Belani study shows that.

3 THE COURT: Should be or is?

4 MR. SACCHET: Is. They conducted it at the
5 University of Minnesota in an ultra clean environment.

6 THE COURT: So the plaintiffs here were all
7 operated on in ultra clean environment?

8 MR. SACCHET: Whether they were all, I don't know.
9 I have not reviewed the 5,000 cases on file. Many of them
10 were.

11 THE COURT: Does it matter? How relevant is it
12 whether we're talking about an ultra clean environment
13 because if you're talking about an increase of one or two
14 particles and that not being acceptable because you're
15 increasing over nothing, then is that a factor that we have
16 to look at with respect to each one of the plaintiffs?

17 MR. SACCHET: Regardless --

18 THE COURT: And whether they were operated on?

19 MR. SACCHET: Regardless of whether there was
20 ultra clean ventilation, the two mechanisms of causation
21 still stand true. There is still a filtration issue that
22 can result in the deposition of bacteria at the surgical
23 site. There still can be convection currents that are --

24 THE COURT: But it doesn't matter.

25 MR. SACCHET: It doesn't change the ultimate

1 inquiry, but it does show that there's an express purpose
2 for downward air flow, which is to remove particles and
3 bacteria from the surgical site, and the Bair Hugger is
4 doing just the opposite.

5 So I would use it as an example to juxtapose what
6 is done to reduce the risk of infection and what the Bair
7 Hugger does in increasing the risk of infection. It's
8 antithetical to what --

9 THE COURT: No. I get it. Don't say it one more
10 time. What, if anything, is in these piles of paper, and I
11 haven't looked at them all, about the air flow disruption
12 effect of a Bair Hugger in a non specialized operating
13 theater, you know, where you don't have the downward flow,
14 and I'm thinking in terms of causation with respect to
15 individual cases.

16 If you've got somebody who was operated on in an
17 environment where you don't have that downward flow, then
18 what is the Bair Hugger air -- how much does the Bair Hugger
19 disrupt the air flow if you are not in that sort of an
20 environment? Is are there any studies about that?

21 The experts, I'm thinking about the science day
22 and everything. Everybody is assuming that you've got the
23 air flowing down, and so if it that's true with respect to
24 all of the plaintiffs, then it doesn't matter. My question
25 is irrelevant, but if it's not and something you don't know

1 if it is, then it seems like something that would have to be
2 reached at the very least with the causation question.

3 MR. SACCHET: I could speculate, but I really
4 don't want to, and I would much prefer to have my colleague
5 address the question when they argue the engineering
6 motions.

7 MAGISTRATE JUDGE NOEL: If anything, it would be
8 worse.

9 THE COURT: I mean I don't know.

10 MR. ASSAAD: I'm happy to answer that question
11 now.

12 THE COURT: Just tell me quickly what it is.

13 MR. ASSAAD: I'll just approach. My friend here,
14 Mr. Sacchet, is correct. It's going to be more of a case
15 specific question on the individual case because we don't
16 know about all of those 5,000 cases what's there, but from
17 an engineering standpoint, what the Bair Hugger does is, it
18 increases the turbulent effect. Now we modelled a uni
19 directional air flow because that is the predominant air
20 flow in most of these orthopedic surgeries.

21 When we get to case specific, we will look at that
22 and see if there's anything different or if the model that
23 we have should be able to be used based on engineering
24 principles, and the engineering principles --

25 THE COURT: Okay. But do you have any modelling

1 of the Bair Hugger air disruption in a non uni directional
2 air flow environment?

3 MR. ASSAAD: Currently?

4 THE COURT: Yes.

5 MR. ASSAAD: No, Your Honor.

6 THE COURT: Okay. Thank you. And thank you,
7 Mr. Sacchet.

8 MR. SACCHET: You're welcome.

9 THE COURT: Mr. Gordon.

10 MR. GORDON: Good morning, Your Honor. May it
11 please the Court. Counsel.

12 It is my goal to try and be as brief as possible.
13 I am, my task is to rebut some of the arguments. If I try
14 to rebut them all, everybody here will hate me. So I'm
15 really going to try to go right for the jugular and right to
16 the key things.

17 THE COURT: Okay. Now, don't take this
18 personally, but I'm always amused by the number of speakers
19 who spend five minutes talking about how they're going to be
20 brief.

21 MR. GORDON: Thank you, Your Honor. Let me see if
22 I can address some questions that came up just in the last
23 few minutes that I wasn't, that I'm not sure were adequately
24 addressed. The Court asked about any studies involving HEPA
25 filter forced air versus non HEPA. It could be found at

1 Document 768-1. I'm sorry. Am I reading this wrong? It's
2 Exhibit 10 to the declaration of Joseph Winebrenner, and I'm
3 sorry to steal Mr. Winebrenner's thunder on this, to the
4 extent he's going to talk about it in connection with the
5 plaintiffs' expert Avid.

6 But this was a study that was done at the
7 Cleveland Clinic. The Cleveland Clinic had used Bair Hugger
8 for a number of years. At some point in 2014, their
9 purchasing department got a better deal on a different
10 forced air warmer unit, Stryker Warm Touch. That does have
11 a HEPA filter. They switched over to that, and so they
12 actually had a couple of years of literally thousands of
13 procedures with that HEPA filter unit versus, you know,
14 thousands of procedures that had been done with the Bair
15 Hugger unit.

16 And they actually did a study where they actually
17 controlled for all the key patient demographics, and they
18 did the various analyses, and what they found was, with the
19 HEPA filter unit, the Stryker Warm Touch, the rate of
20 infection -- well, first the punch line. No statistically
21 significant difference between the two, but with respect to
22 the raw numbers, the superficial infections, they broke it
23 out.

24 The superficial infections with the HEPA filter
25 unit were .84 percent. With the FAW or Bair Hugger, it was

1 1.8 percent. It was not statistically significant. The
2 flip side of that was, with the HEPA filter unit, it was .77
3 for the deep joint infections, .47 for the Bair Hugger.
4 Again, it didn't quite make a statistical significance, but
5 to the extent that they want to talk about a HEPA filter as
6 a theoretical construct, these are real data.

7 THE COURT: So that would at an anti HEPA filter
8 confounder piece of evidence.

9 MR. GORDON: At best, it shows the HEPA filter
10 makes zero difference.

11 THE COURT: And that's Exhibit 10 to the
12 Winebrenner?

13 MR. GORDON: Yes.

14 MAGISTRATE JUDGE NOEL: Why didn't ECRI recommend
15 that they all have HEPA filters?

16 MR. GORDON: There's a -- I'm not going to try to
17 get into in the weeds. There's a mystique about HEPA
18 filters. HEPA filtration is a filtration concept that was
19 designed for clean rooms for the making of micro chips,
20 where any tiny little particle can mess up the chip. A HEPA
21 filter filters out 99.97 percent of .3 size micron
22 particles, very, very, very tiny particles.

23 And if you're interested in keeping your micro
24 chips clean, then that's a good thing, but if you are for
25 some reason trying to filter out fungal spores that can get

1 down to that size, that's a good thing. If your interest,
2 if your focus is filtering out bacteria, the extra value of
3 going down to the .3 micron level of filtration, there's no
4 there there because the smallest bacterium that causes
5 infections and joint infections specifically is just under
6 1 micron .7, .8, .9 depending on which bacteria you want to
7 look at.

8 So that extra benefit for filtering out really
9 tiny particles, there is no there there, which is why, and
10 again I'm stealing other's thunder, the standard for
11 operating room filtration is not HEPA. It's MERV14. That
12 being said, there's a perception. There is a perception
13 amongst doctors. There's a perception among lots of people
14 that HEPA is better. If we use a HEPA, that's even cleaner,
15 and that's even better.

16 In the abstract sense, yes, but in terms of what
17 matters, the bacteria, it doesn't, it doesn't add anything
18 over a MERV14, which is what is recommended, which is what
19 happens to be the filter in the Bair Hugger.

20 THE COURT: So the MERV14, is that lower than
21 10 microns? What's the particle size that they're talking
22 about, 10 microns?

23 MAGISTRATE JUDGE NOEL: I don't know.

24 MR. GORDON: MERV14, it doesn't focus on one
25 specific category. It has different ranges, and my partner,

1 Pete Goss, will give you more detail on this, but at the
2 level that matters for us, .7, .8, .9, the MERV14 requires I
3 believe -- I don't want to caveat this. I'm not certain of
4 this, but I think it's 90 percent. The MERV1414 filter
5 that's in the Bair Hugger --

6 THE COURT: If you don't mind one last question
7 about HEPA filter. Is it obvious if are you hospital or a
8 doctor or even a lay person, when you look at a filter, do
9 you know whether you've been sold an HEPA or non HEPA
10 filter?

11 MR. GORDON: I don't believe so, Your Honor.

12 THE COURT: So you might be fooled into buying a
13 filter that's HEPA and is not. If you go to Best Buy and
14 pay a hundred dollars, they put a HEPA filter on vacuum
15 cleaners. If you have ever cleaned your house, you would
16 know that.

17 MAGISTRATE JUDGE NOEL: I guarantee you if you're
18 talking about vacuum cleaners and stuff you buy at Best Buy,
19 HEPA they sell it. It's a big thing.

20 THE COURT: I know, but I'm saying --

21 MAGISTRATE JUDGE NOEL: It is not like you can get
22 a Bair Hugger at Wal-Mart.

23 MR. GORDON: I was actually going to talk about
24 vacuum cleaners in response to your question.

25 THE COURT: So if you know what you're looking for

1 and you look at your filter, do you know whether you have a
2 HEPA or non HEPA filter?

3 MR. GORDON: Not just by eyeballing it, no. You
4 would have to have testing. You would have to have some
5 representation as to what it is. Specifically, with respect
6 to vacuum cleaners, the FTC has come down on a couple of
7 manufacturers of vacuum cleaners who are marketing their
8 products as having true HEPA filters, and they did it, but
9 they were marketing it so it made a difference.

10 THE COURT: My questions go to plaintiffs' point
11 about the FDA being hoodwinked about there being a HEPA
12 filter. Anyway --

13 MR. GORDON: And actually, Your Honor, I will
14 leave it to others to go into the details on that because,
15 because I got a lot of other things that I probably need to
16 address. We didn't get that early draft until essentially
17 the end of, well, it wasn't the very end of discovery, but
18 it was after all of the study authors, except Dr. McGovern,
19 had been deposed. It was Dr. McGovern who produced that.
20 That was when we had an opportunity.

21 So Nachtsheim, Albrecht, Reed, any of the other
22 authors you want to name, they had not been deposed after we
23 got that. So no one was asked any questions about that
24 preliminary draft, except Dr. McGovern. He knew nothing
25 about it. Why? Again, this is an important point to

1 remember.

2 Dr. McGovern was a young resident at Wansbeck
3 Hospital at the beginning of the McGovern paper. All he did
4 was participate in the bubble portion of it. By the time
5 they started switching over to HotDog, he was already at
6 another hospital. He was already doing something else and
7 had nothing to do with the data collection, nothing to do
8 with data analysis.

9 And so the fact that he's I know nothing, that's
10 true. He didn't. He just happened to have all of the
11 documents because he was cc'd on everything as they were
12 going back and forth and drafting them. And I also to that
13 point, the fact that Dr. McGovern, quote, "stands by it," I
14 don't know what that means because he says, well, yeah this
15 is what's in the paper. Yes, that's what was reported.

16 He has no independent knowledge. He has no
17 personal knowledge. He has no participation. What they
18 don't quote is Dr. Reed or Dr. Albrecht, both of whom
19 conceded lots of confounders, lots of reasons to think that,
20 you know, is it live? Is it Memorex? No. This association
21 that we are reporting, it's just that. Maybe it will spur
22 some further investigation, but there are lots of
23 confounders.

24 MAGISTRATE JUDGE NOEL: Are you saying that Reed
25 and Albrecht disclaimed the association and don't stand

1 behind the McGovern report?

2 MR. GORDON: They make it very clear that all they
3 were reporting was, there were these many infections in one
4 group, these many infections in another group. If you just
5 look at those two factors, these are the numbers, and even
6 on that point, Dr. Reed volunteered, we made a mistake.
7 There should have been one more infection report, he said,
8 in both the HotDog and the Bair Hugger period.

9 That wouldn't change things. It actually does,
10 but the important point is that all he or McGovern are
11 standing behind, and they repeatedly said, you know, this is
12 just an observational study. We're not drawing any
13 conclusions. It's wrong to draw conclusions from it. It
14 does not -- it's, yes, there is an association reported.

15 And you know, hopefully others will do further
16 studies and see if there is any there there. They didn't
17 control for confounders. They acknowledge that, and we've
18 heard several times how, well, the effect continued because
19 they collected six months more of data. Here's the problem
20 with that. What they're doing, they could extend the post
21 switch collection to infinity.

22 The fact that somehow the rate was up here in one
23 period of time and it got down to here and stays down here
24 indefinitely, the longer you go out there doesn't change the
25 fact that the reason it got from the high to the low cannot

1 be attributed just to the Bair Hugger. There were multiple
2 things going on, multiple confounders, multiple changes that
3 I want to talk about very briefly that are addressed
4 extensively, substantively by Dr. Borak, by Dr. Wenzel, by
5 Dr. Mont, statistically by Dr. Holford.

6 Let me just talk about the Nachtsheim deposition
7 because I started out with that, the Figure 7. I believe
8 the suggestion was that Dr. Nachtsheim had testified that he
9 was the one who decided lets flatten out that graph and just
10 use an average across the whole time period. Could I have
11 the Nachtsheim?

12 So the decision about where to draw lines and
13 period where forced air warming transition and conductive
14 warming you. No I.

15 Question: Did not have --

16 Answer: No.

17 -- any involvement in those, any discussion about
18 that?

19 Answer: I had no involvement. There was no
20 discussion. This was just the, the data were presented to
21 me. Here it is, you know. This is the transition period.
22 Here is before and after.

23 Question: Other than suggesting to Mark Albrecht
24 that he add the confidence intervals to results that are
25 presented in Figure 7, do you recall providing Mark with any

1 input or guidance or suggestion about either the design or
2 the statistical work that's reflected in Exhibit 4 --
3 Exhibit 4 was the McGovern study -- with respect to
4 infection data?

5 Answer: No.

6 And another point that I want to clear up right
7 away is the so-called missing data, the data that
8 Dr. Holford analyzed. We heard quite a bit about that,
9 quite a bit about it in their reply brief, not in the
10 opening brief, but the reply brief talks about this missing
11 pages. So my gosh this September 2008, there's the smoking
12 gun.

13 We also heard yesterday an interesting point that
14 the data in Albrecht Exhibit 10, you can't analyze it. It's
15 not machine analyzable. It's just a photocopy. Yeah.
16 That's true. Dr. Holford didn't analyze the photocopy. He
17 didn't analyze the raw data printed out by someone. He
18 analyzed the electronic file. The electronic file was what
19 was provided in response to the subpoena by Augustine.

20 That was provided to both the plaintiffs and the
21 defendants. That was provided, the electronic file, was
22 provided to Dr. Holford. His analysis is based on the
23 electronic file. At Dr. Holford's exhibit, counsel handed
24 him a photocopy of Albrecht Exhibit 10, and I dug up the
25 copy that I got when I was sitting at the deposition,

1 because I, you know, when I'm handed a copy, I write quickly
2 what it is, and then I put it in my bag.

3 So this is a copy of what was handed out at
4 Dr. Holford's deposition, and sure enough there's a missing
5 page. Here's the missing page, because we had it.
6 Plaintiffs had it, and I'm happy to provide it to counsel to
7 make it easier for them. I have copies for the Court.

8 THE COURT: No.

9 MR. GORDON: If the Court is interested.
10 Remember. This is the ominous suggestion that this missing
11 page that's got the column with infection data from that
12 September 2008 time period, and if we just had that, we
13 would see one of those infection corresponds to one of those
14 dots.

15 The column, there is only one column on it that
16 has anything on it. It would either have a Y or an N for
17 infection. Every single one of them is N. So there was no
18 missing page from what was provided to -- by the way, I'm
19 not suggesting in any way that anyone made an intentional
20 error in omitting that particular page from an exhibit, from
21 a photocopy.

22 I'm sure it's a photocopying error, but this is
23 not what Dr. Holford analyzed. He analyzed the electronic
24 file, and it was complete. Now, aside from that, we've been
25 told, well, that's terrible, horrible, no good evidence. We

1 have no idea whether these data are the right ones.

2 Here are the reasons why it's reliable. Number
3 one, Mr. Albrecht was asked, who has the data? Do you have
4 the data? He no longer had it. He said, Augustine would
5 have the data, and Augustine was asked to produce the
6 underlying McGovern data and did so in response to a
7 subpoena.

8 When Albrecht looked at, and to be candid, he
9 didn't have the electronic file to look at. We just, we
10 made a printout of an Xcel spreadsheet, which is almost
11 impossible to view, but just to have something to put in the
12 record, you know, are these the data? He said they were
13 probably the updated set provided to him by Reed. He wasn't
14 certain, but he said probably.

15 Reed looked at it, and he said, In all honesty it
16 looks like it. I don't know if it is what I gave, but I
17 don't know how he would have gotten it if it wasn't from me.
18 Good point. Where else did these come from?

19 And these data were completely 100 percent
20 consistent with that reduced graph, chart that was marked as
21 McGovern Exhibit 16 where just the infection data were
22 called out. It not even a difference. It's exactly
23 consistent in terms of the date, the type of infection, the
24 age, the type of procedure, et cetera, et cetera.
25 Completely consistent.

1 And it's entirely consistent with the data that
2 were published if you just move that one, if you reclassify
3 that one HotDog procedure as a Bair Hugger procedure. It's
4 also, I might add, completely consistent with the
5 penultimate version, version 10. There were no other raw
6 data produced by any of the coauthors.

7 We couldn't force Reed to produce anything under
8 English law. No one else produced anything, and no other
9 witnesses -- these are the data, and one final thing.
10 Again, it was electronic data. So we looked at the meta
11 data, and as we can see, the meta data from what was marked
12 as Albrecht 10, but the electronic file of it, was last
13 modified by Mike Reed, February 24, 2011.

14 The significance of February 24, 2011, is that
15 it's just about 63 days after the last procedure that they
16 included in their analysis, and since they had decided to
17 use a 60-day window, they would have had to have waited
18 until right around the end of February to see if there were
19 any other infections before they could report data through
20 the end of December.

21 So that is the story on the validity of the data
22 here. With that said, again, Professor Holford's -- and one
23 final thing. Plaintiffs say that Dr. Reed testified the
24 published data was definitely correct. Actually, what
25 Dr. Reed said was, the original file I sent to Albrecht for

1 the paper was definitely correct. It was. It was
2 definitely correct.

3 The re-coding of the single infection, that's not
4 what Reed was testifying about. We didn't know it at the
5 time and didn't have the opportunity to ask about it. What
6 he was testifying to was that the data file that he sent to
7 Albrecht, and remember he also said, you know, there should
8 have been one more infection in each group, he said, and I
9 don't know why Mark didn't -- I don't know why Albrecht
10 didn't make that correction.

11 I don't, either. I have my ideas. Let me see if
12 I can just now quickly jump through -- there's several
13 points. I was surprised again. This morning counsel said
14 that in order for somebody to be a confounder that there
15 must be a substantial difference.

16 In our response brief, we said that that's what
17 plaintiffs were arguing. In their reply brief they said,
18 no, no, we're not arguing that it has to be a substantial
19 difference. Really couldn't argue that given that Dr. Samet
20 agrees. No. For something to be confounder, you don't have
21 to have independent, statistically significant impact. It
22 just has to be associated.

23 And I would love to take the Court's time. I
24 won't. I'm just saying I'd love to, going through in great
25 detail all of the various confounders, all the various

1 things that were mentioned that weren't considered that
2 weren't analyzed and things that weren't.

3 And I do want to talk about one of the mentioned
4 confounders, the patient characteristics, the like fitness
5 for surgery, because there was an argument made that well,
6 that doesn't introduce bacteria to the wound. Aside from
7 the fact that some patient factors actually can. Obesity,
8 for example, increases the bio burden that the patient
9 brings to the table, and it makes it that much harder to
10 eradicate the patient's own natural bacteria.

11 But the point is, if say you had a hundred
12 patients with an ASA score, a high one of five in one cohort
13 and a hundred patients with an ASA score of one, and the
14 first group was done with Bair Hugger and the second group
15 was done with HotDog, and you had a much higher infection
16 rate with the Bair Hugger group, and you didn't factor in
17 the fact that there was a difference in the ASA scores, the
18 fitness for surgery measurement, then you can't, you cannot
19 draw a conclusion.

20 That is a systemic bias that cannot be controlled
21 for in the technical terms. What it means is, they don't
22 know. They admit, and they acknowledge that. That's one of
23 the unfortunatelys in the McGovern paper. They have -- they
24 could have gone back and pulled the data, but they opted not
25 to.

1 Again, it's just an observational study. They are
2 just recording their numbers and hoping there would be other
3 research done, but the fact that they said, you know, we're
4 saying these patient factors have been independently
5 associated with. That means their confounders,
6 independently identified as risk factors, and we haven't
7 controlled for them. We don't have numbers. We don't know.
8 You can't draw any conclusions. There is no association
9 that can be gleaned from that. Yeah, there's a number.

10 THE COURT: Okay. So Borak and Holford and Mont
11 and Wenzel were all working together; is that right?

12 MR. GORDON: Directly working together, I want to
13 say Borak, Holford and Wenzel. In fact they had a meeting
14 together, and that was explored in discovery. Mont didn't
15 physically meet with them but was providing information back
16 and forth.

17 THE COURT: And are you going to address Mont and
18 Wenzel as well?

19 MR. GORDON: My partner Mary Young is going to
20 talk about Dr. Wenzel.

21 THE COURT: So I'm inclined to mostly take Mont
22 and Wenzel on the papers, but I want to briefly hear from
23 whoever on the plaintiffs' side is going to speak about
24 those two, and then I want just a brief response from you
25 and Ms. Young on those two.

1 MR. GORDON: Thank you. And at this point I'm
2 going to stop, but I just don't want my failure to address
3 multiple other things to be construed as acquiescence. I
4 think we've addressed many of the things in our brief.

5 THE COURT: Thank you, Mr. Gordon.

6 MR. GORDON: Thank you.

7 THE COURT: We're going to take a 10-minute
8 recess.

9 (Recess at 10:30 a.m.)

10

11 (10:40 a.m.)

12 THE COURT: Welcome back, and please go ahead and
13 be seated everybody.

14 MR. ASSAAD: Thank you, Your Honor. Just before I
15 begin, I know the Court wants me to be brief. I just want
16 to know just an estimate of how much time I will have so I
17 know what slides to focus on and what slides not to focus
18 on.

19 THE COURT: 15 minutes.

20 MR. ASSAAD: 15 minutes? Thank you.

21 MAGISTRATE JUDGE NOEL: I'm sorry, just so that
22 I'm clear, which is -- what are we talking about now, this
23 is?

24 MR. ASSAAD: Mont.

25 MAGISTRATE JUDGE NOEL: Mont.

1 THE COURT: Oh, I thought you had Mont and Wenzel.

2 MR. ASSAAD: No, my colleague Ms. Zimmerman will
3 be doing Wenzel.

4 THE COURT: That's right.

5 MAGISTRATE JUDGE NOEL: This is Michael Mont.

6 MR. ASSAAD: Yes.

7 MAGISTRATE JUDGE NOEL: Got it. Thank you.

8 MR. ASSAAD: I will go as quickly as I can, Your
9 Honor, without going too fast for the court reporter.

10 First of all, Your Honor, we do not dispute
11 Dr. Mont's qualifications as an orthopedic surgeon. He is
12 clearly qualified to testify about implant surgeries as it
13 is aware from record the record that he has done many
14 implant surgeries. But it's undisputed that Dr. Month has
15 no education, training, or experience in heat transfer or
16 fluid dynamics. Dr. Mont does not dispute that bacteria
17 causes periprosthetic joint infections. In fact, he even
18 said that the device causes bacteria into the sterile field,
19 he would not want to be using that device.

20 This case is different, as my colleague said,
21 between the *Glastetter* case. In that case, it was whether
22 the drug caused vasal constriction. There is no question on
23 both sides that bacteria is a biological agent that causes
24 periprosthetic joint infections, that it occurs at the time
25 of surgery, and the mechanism is established by the studies

1 as well as the engineering evidence.

2 The journal causation question here is does the
3 Bair Hugger cause bacteria to reach the surgical site during
4 surgery? And Dr. Mont agrees with many of the opinions that
5 the plaintiffs proffer. The majority of prosthetic joint
6 infections are initiated through introduction of
7 microorganisms at the time of surgery. Strategies should be
8 used utilized to lower particulate and bacterial counts at
9 the surgical site. The probability of surgical site
10 infection correlates directly with the quantity of bacteria
11 that reach the surgical wounds.

12 Disruption of either direction air flow in an
13 operating room can potentially cause the instruments, hands
14 of the surgeon, and implant to become contaminated. Fewer
15 colony forming units are required to cause a periprosthetic
16 joint infection than a superficial wound infection.
17 Orthopedic surgeons would be concerned if a device was from
18 raising bioburden from underneath the operating room table
19 into the surgical site.

20 Now, we talked about the international consensus
21 of periprosthetic joint infection. I just want to mention
22 -- the national consensus. That entire consensus dealt with
23 periprosthetic join infections and not superficial wound
24 infections, and I just want to make clear that everything in
25 the international consensus deals with periprosthetic joint

1 infections as it's been titled. And in fact, Dr. Mont was
2 an attendee of the international consensus, and he said
3 during his deposition that he thinks it's very
4 authoritative. And therefore, he agrees, during his
5 deposition, according to the international consensus of
6 orthopedic surgeons that voted on this, over 400, as the
7 defense has indicated, the numbers of bacteria arriving in
8 the surgical wound correlate directly with the probability
9 of surgical site infection. We recognize the probability of
10 SSI correlates directly with the quantity of bacteria that
11 reach the wound. 97 percent agree, strong consensus.

12 Do the numbers of bacteria in the operating room
13 environment correlate directly the with the probability of
14 surgical site infection? We recognize that airborne
15 particulate bacteria are a major source of contamination in
16 the operating room environment and that bacteria shed by
17 personnel are the predominant source of these particles.
18 The focus of our recommendation is to reduce the volume of
19 bacteria in the operating room with particular attention to
20 airborne particles. This is the international consensus,
21 generally accepted opinions of methodology, 93 percent.

22 And they give justification for that. Air is a
23 potential source of contamination in the operating room.
24 Studies have demonstrated that the number of airborne
25 bacteria around the wound is correlated with the incidence

1 of PJI. It has been suggested that if it was possible to
2 measure accurately the number of bacteria present in the
3 wound, it should constitute the most precise predictor of a
4 subsequent infection.

5 Bacteria can be considered as part of a total mass
6 of particulates in the air. Some studies have suggested
7 that airborne particulate count, not bacteria count,
8 particulate count, should be considered as a potential
9 surrogate for airborne microbial density. Others have found
10 correlation between the number of particulates larger than
11 ten micrometers with the density of viable bacteria at the
12 site of the surgery measured by colony forming units. And I
13 remember you were referring to the size of the particles.
14 That is one of the reasons why we used ten micrometers for
15 the size of the particles.

16 It has been suggested that monitoring particle
17 counts can be used as a realtime proxy for increased risk of
18 wound contamination or infection. Persons in the operating
19 room, persons, are a major source of bacterial load and shed
20 bacterial particulates. These particulates circulate
21 through the operating room via air currents. Movements of
22 objects can generate significant marked air currents and
23 increase the probability of bacteria being deposited at the
24 surgical site.

25 MAGISTRATE JUDGE NOEL: Well, let me ask another

1 question related to this question of what is and is not in
2 dispute. As I understand it, one of the factoids in the
3 case relates to whether bacteria travelled on particles, and
4 there's a question in my mind about the size of the
5 particles. Is there some consensus between the parties
6 regarding what sized particle can carry bacteria?

7 MR. ASSAAD: I will speak on behalf of the
8 plaintiffs because I will rely on the studies. The studies
9 have shown, which was a stock study, that you could
10 correlate particles to bacteria regarding 10 micron -- 10
11 micron particles correlate directly with the biodensity or
12 the density of the bacteria over the surgical site. There's
13 other studies from the 60's and 70's, Celon and Clark, that
14 have also looked at you could correlate particles and I
15 think they said about five microns with bacteria.
16 Darouiche, 2017, correlated all particles to bacteria.

17 MAGISTRATE JUDGE NOEL: Regardless of size?

18 MR. ASSAAD: Regardless of size. However, as a
19 conservative approach, the plaintiffs took the worst case
20 scenario of 10 microns when we did our CFD study. Bacteria
21 alone can be aerosolized on its own as well as skin squames.
22 And that I think is a good question, Judge Noel, because
23 when we talk about particles here, we're really talking
24 about skin squames, and that's why the international
25 consensus, over 400 surgeons, all agree that the persons in

1 the operating room are a major source of bacterial load and
2 shed bacteria particulates through skin squames.

3 And ASHRAE, the American Society of Heating and
4 Ventilation -- or Refrigeration and Ventilation, and other
5 studies have indicated between a two- and four-hour surgery,
6 between 1 million and 900 million skin squames are deposited
7 throughout the surgery by the patients to the floor. Not
8 only that, Dr. --- I mean, all the physicians agree, all the
9 experts agree that the skin squames deposit, and Dr. Mont
10 even testified that there's more bacteria on a person than
11 there is skin cells. And that is why Dr. Wenzel testified,
12 their expert, that 40 percent of the particles in the
13 operating room, which are mostly skin squames contain
14 bacteria.

15 MAGISTRATE JUDGE NOEL: So just to make sure I
16 understood your answer, there is some dispute about that
17 between your experts and their experts or all the experts
18 agree to all of the statements you just made?

19 MR. ASSAAD: I think the dispute will be what size
20 particle, but I think there is uniformity that there's
21 bacteria in the operating room and they could be carried on
22 particles. The question is whether it's a ten micron or
23 five micron or one micron.

24 MAGISTRATE JUDGE NOEL: But you're saying your
25 experts for all of the studies that they've done have only

1 opined on the making a particle a proxy for bacteria as to
2 those particles that are ten microns or greater?

3 MR. ASSAAD: As a very, very conservative approach
4 for the model. However --

5 MAGISTRATE JUDGE NOEL: That's a yes?

6 MR. ASSAAD: Yes.

7 MAGISTRATE JUDGE NOEL: Okay.

8 MR. ASSAAD: Yes. But if you have a five micron,
9 the intensity, the effect of the buoyancy and all the
10 forces, which are generally accepted principles, would also
11 cause the particles to rise.

12 MAGISTRATE JUDGE NOEL: Thank you.

13 MR. ASSAAD: This question is the question -- or
14 with respect to forced-air warming blankets, and I want to
15 address it really quick. So if you recognize the
16 theoretical risk posed by the forced-air warming blanket and
17 that no studies have shown an increase in SSI related to the
18 use of these devices, we recommend further study but no
19 change to the current practice. I would like the Court to
20 notice that with questions one with respect to bacteria and
21 the amount of bacteria, they didn't request further study to
22 be required. And this was in 2013. And I would also like
23 to point --

24 THE COURT: But you're really -- would you go back
25 to that statement? So this is an international consensus

1 which it seems that there is no dispute as between the
2 plaintiffs and the defendants about the righteousness about
3 of that convention.

4 MR. ASSAAD: There is a little bit of a dispute,
5 and if you look a couple of more slides, you'll see that the
6 primary sponsor of that convention was 3M.

7 THE COURT: Okay. Well, is that your -- so I mean
8 you thought you were relying on things?

9 MR. ASSAAD: I --

10 THE COURT: What's your view of that convention?

11 MR. ASSAAD: What the general is consensus is
12 relying on here is published studies, and I rely on those
13 published studies, and I agree with the international
14 consensus. I also --

15 THE COURT: So that's fine.

16 MR. ASSAAD: Yeah. Sorry to interrupt, Your
17 Honor.

18 THE COURT: So the international consensus then is
19 that there are no studies that have shown an increase in
20 SSI, we recommend further study but no change to current
21 practice, and they recommend no change to what's actually
22 going on in hip and knee implants but further study. And so
23 you're saying is that further study ought to take place in
24 the courtroom before it takes place out in the real world,
25 such that then in a courtroom we could say, okay, there's

1 been further study and it shows that there is a correlation
2 or a causation. So the causation is to happen in court?

3 MR. ASSAAD: No. No, Your Honor. We actually
4 performed the further study. We actually did a
5 computational fluids dynamic test, and there's other studies
6 that our experts relied upon, but if --

7 THE COURT: Was that in 2013?

8 MR. ASSAAD: This was 2013. And since 2013 there
9 's been other studies. There's been the Stock study.
10 There's been the Darouiche study.

11 THE COURT: What's the current international
12 consensus? Or don't we know?

13 MR. ASSAAD: I think they're meeting, and I'm sure
14 since 3M is sponsoring it, I'm not sure if they're meeting
15 this year or next year.

16 MR. BLACKWELL: Don't look this way.

17 MR. ASSAAD: I know there's some testimony, and I
18 forget from who, that they're meeting again very soon, maybe
19 in 2019. I don't know how long it's going to take. But
20 further studies required. It's not like the other studies.
21 We've done the study. This is an engineering question here.
22 This is not a what causes an infection because we all know
23 and agree bacteria causes the periprosthetic joint
24 infection.

25 THE COURT: But by further study I don't think

1 they meant litigation related study?

2 MR. ASSAAD: Well, it just says further study.
3 And if you look regarding the safety and the efficacy of
4 forced-air warming, 3M, who was putting this product out,
5 has made a decision at the highest level not to pursue
6 clinical research work on the safety and efficacy of
7 forced-air warming.

8 THE COURT: Well, what are we to make of that? I
9 mean, that -- the punitive damage question has passed. So
10 when they say further study, does that mean if 3M is not
11 going to do it, then it has to be done for litigation
12 purposes? Is that what you're saying?

13 MR. ASSAAD: If that's part of the litigation,
14 Your Honor, is sometimes litigation leads science and forces
15 science to move forward.

16 THE COURT: So when that happens, of course, not
17 infrequently when there is some sort of new science, but
18 here we've got something that's been around for 20 or 30
19 years and the international consensus is that the state of
20 things as of now is there's no -- it doesn't -- whatever the
21 words were that they said.

22 MR. ASSAAD: 2013. Not the state of now. That
23 was 2013.

24 THE COURT: Well, at the time that the -- I don't
25 know what it is.

1 MR. ASSAAD: Yes, but they didn't have the --

2 THE COURT: Well, they don't have anything newer,
3 so I mean --

4 MR. ASSAAD: Right. And that is our case, Your
5 Honor, we have new studies, we've had people look at all the
6 studies, and there's the Legg study, there's the Kurz study
7 that looked at the heat -- Kurz who was a 3M advisory looked
8 at when use the Bair Hugger, the heat increases around the
9 operating room table, the heat comes from the Bair Hugger,
10 the heat is what causes the turbulence that causes the
11 eddies which I'll explain in the engineering presentation.

12 THE COURT: But this has been going on for
13 30 years.

14 MR. ASSAAD: Lot of things goes on for 30 years
15 and science catches up and, you know --

16 THE COURT: But science hasn't caught up. I mean,
17 you're making science catch up because we just saw what
18 science says. Science says we don't see it.

19 MAGISTRATE JUDGE NOEL: Well --

20 MR. ASSAAD: In 2013. But we've done studies
21 ourselves. I'm sorry, Judge Noel.

22 MAGISTRATE JUDGE NOEL: I was just going to say
23 that as I understand the recommendation of this
24 international consensus was that more studies should be
25 done.

1 MR. ASSAAD: Yes.

2 MAGISTRATE JUDGE NOEL: There is a question here
3 that needs to be addressed.

4 MR. ASSAAD: The question is still open. They
5 have not said -- unlike the other two that bacteria causes
6 infections and the amount, they said further research is
7 required. And it's kind of funny because it also says
8 further research is required for maintaining normothermia in
9 orthopedic patients, and I'll show you that slide in a
10 second. But further research is required, and that is what
11 the plaintiffs did. We went out got one of the premier
12 epidemiologists. We got the premier computational fluid
13 dynamics expert in particle flow which relies on not theory
14 but mathematical equations that they use to launch rockets,
15 do CFD studies on nuclear explosions, on stuff that is high
16 level, and we'll be explaining in engineering. The studies
17 have been done by the plaintiff, and those are the studies,
18 and as well as Darouiche and Stocks and all the stuff that
19 the epidemiologist is relying on.

20 I put the slide in just now because of the
21 Moretti, but the international consensus states that Moretti
22 undertook air sampling in experimental conditions and
23 demonstrated an increased bacterial contamination of the air
24 after turning forced-air warming blankets on; however, this
25 was much lower than worsening of air quality induced by the

1 personnel placing a patient in the OR. That's the
2 difference in Moretti. When you compare -- when they're
3 putting -- you have all the people around, the patient's
4 moving, they're moving the equipment, that's when know did
5 the bacteria test and that's why we have to look at Moretti
6 saying, Moretti increased the bacterial load when you looked
7 at the OR compared to -- OR at rest compared to when the
8 Bair Hugger was on.

9 THE COURT: Well, the OR at rest was before the
10 patient was moved?

11 MR. ASSAAD: Yes, but when you're moving the
12 patient -- and Dr. Mont and others agreed with the Moretti
13 when I quested about it, probably the highest burden of
14 bacteria and particles is when you're prepping the patient,
15 you have the nurses coming in and out, moving up and down
16 the drapes, putting on the Bair Hugger, before everything
17 calms down, the operation is set, and then at that point in
18 time --

19 THE COURT: The problem is that that Moretti
20 didn't study it after the calm down?

21 MR. ASSAAD: Exactly. Exactly. And I just want
22 to point this out, Your Honor. Does patient normothermia
23 have an essential role in preventing infectious
24 complications? And they support general surgery but they
25 also say that it requires further research. And at the

1 bottom it says, No such RCT was identified specifically for
2 TJA or orthopedic procedures in general. The international
3 consensus also thinks this is an open question and that they
4 understand that the Kurz study was on colorectal.

5 And let me tell you something about the Kurz
6 study, Your Honor. We talked about -- and this is for Judge
7 Leary about who sponsors. Augustine sponsored the Kurz
8 study. It was Augustine at the time. It was Scott
9 Augustine. And at the time, the reason that Dr. Kurz said
10 it was not scientific accurate at this point in time is they
11 actually cooled the control group. They actually blowed
12 cold air on the control group which it would be unethical
13 today to do to blow cold air. So every study has its
14 limitations. Every study has its issues, the Kurz study,
15 which is the only study this relies on. Melling which they
16 rely on here is a pre-warming study. It has nothing do with
17 intraoperative warming.

18 THE COURT: So let me just ask you one more time.
19 You refer to the international consensus sometimes like it's
20 really the international consensus but then other times you
21 kind of poopoo it by saying 3M sponsored it. So what is it
22 your view? Is it -- can we take this as an international
23 consensus or do you say the whole thing is tainted --

24 MR. ASSAAD: We take it as something that both
25 sides can rely upon.

1 THE COURT: Okay. So the international consensus
2 is okay and the fact that it had a sponsor, they weren't
3 influenced by -- you're not alleging that --

4 MR. ASSAAD: It may or may not, I don't know, Your
5 Honor. We do have that Michelle Hulse Stevens.

6 THE COURT: I just want to know, I can't tell
7 whether you're for it or against it. I mean, when it says
8 something you don't --

9 MR. ASSAAD: I --

10 THE COURT REPORTER: One at a time.

11 MR. ASSAAD: I'm sorry. Sorry, Your Honor.

12 I believe it's one source of information. We rely
13 upon it. It's one of the reliable documents that we rely
14 upon it.

15 THE COURT: Okay.

16 MR. ASSAAD: But it also says it's an open
17 question with respect to forced-air warming.

18 The summary of Dr. Mont's opinions, every device
19 or instrument is a potential source of bacteria except the
20 Bair Hugger. That's his opinion. Everything in the
21 operating room is a potential source of bacteria or
22 contamination except for the Bair Hugger which blows heat
23 and it's not sterile.

24 Plaintiffs conclude the following things with Dr.
25 Mont. They are many sources of heat generation in the OR,

1 more significant than the Bair Hugger and other devices that
2 have fans impact airflow in the OR. There's no evidence
3 that produces more airflow and heat than the Bair Hugger in
4 the OR.

5 We agree with the holding that Judge Noel in
6 *Luminara* that said, It is common for experts to rely on
7 information outside of their field of expertise in rendering
8 expert opinions. We have no dispute with that. However,
9 the information the expert relies upon must be cited and it
10 must state what the expert claims it states.

11 Dr. Mont does not know about all of the devices he
12 says that produce heat, how much heat each device has. He
13 does not know when he says this device, a monitor or an
14 anesthesia machine, blows air, he doesn't know the quantity
15 of air. So he has to rely on other studies because he did
16 not do any experiments and he's not a fluid or heat transfer
17 engineer.

18 Dr. Mont provided no citations in his expert
19 report. He attached Exhibit A, which was required by the
20 rule, Federal Rules of Civil Procedure, all the documents he
21 considered, and he put down about 120 documents he
22 considered, but that doesn't meet the Federal Rules of Civil
23 Procedure where a complete statement of all opinions the
24 witness will express and the basis and reasons for them. In
25 his report and even during this deposition he said this

1 causes air, this causes heat but would not -- he did not
2 know what he was referring to, he did not say he was
3 referring to or put any type of reference.

4 It wasn't until we filed our motion that the
5 lawyers came back with a couple of the citations, not all of
6 them, a few examples, of where and what Dr. Mont was relying
7 upon. He had plenty of time to review his report, to
8 prepare his report. He was required under the Rules of
9 Federal Procedure 26, and he's no stranger to litigation,
10 he's testified numerous times, he failed to identify the
11 basis for many of his opinions that are outside of his
12 expertise and therefore his opinions on the devices that
13 produce air and heat must be excluded. If there are no
14 questions, I will pass it to the defense.

15 THE COURT: Thank you.

16 MR. GORDON: Thank you, Your Honor. I just want
17 to clarify that 3M did indeed was a cosponsor of the
18 international consensus, along with dozens of others --
19 pretty much every medical device or supplier of things that
20 orthopedists might be interested in cosponsored the
21 convention.

22 One more thing, I've been in a lot of trials where
23 the other lawyer says to the jury, now, ladies and gentlemen
24 of the jury, what I say is not evidence. I never say that
25 because I don't really want to undercut what I'm saying, but

1 it's true what the lawyer says is not evidence. I just, I
2 feel compelled to urge the Court to review what's actual --
3 you know, the record actually is, what the studies actually
4 say, what Dr. Mont actually testified to because I don't
5 want to go into any detail as to where there have been
6 misrepresentations or mischaracterizations of these things,
7 and with that, we will rest on our pleadings.

8 MAGISTRATE JUDGE NOEL: Let me just ask one
9 question of it. So one of the things that struck me about
10 the presentation and reading the memo that Dr. Mont
11 testifies that a number of other items in the operating room
12 can be the source of heat, can be the source of bacteria,
13 correct?

14 MR. GORDON: I believe specifically what he was
15 saying was virtually anything in the operating room can
16 harbor bacteria and you can, if you swabbed everything in
17 the OR, you would find bacteria.

18 MAGISTRATE JUDGE NOEL: Including the Bair Hugger?

19 MR. GORDON: Including the Bair Hugger,
20 absolutely.

21 MAGISTRATE JUDGE NOEL: So when they say that he
22 testified that all these things other things could be
23 sources except the Bair Hugger, that's a spin?

24 MR. GORDON: I think so.

25 JUDGE LEARY: I have a question, and it's really

1 by way of background. Maybe you're not the best person on
2 your team to answer this question, but is there a specialty
3 within the operating suite that has primary responsibility
4 for the use and operation and safety of the equipment that's
5 contained? We've talked a lot about orthopedic surgeons and
6 their view with regard to infection and surgical sites, deep
7 joint infections, but I'm not sure that that stands for the
8 proposition that orthopedic surgeons are the ones who order
9 the warming devices that are otherwise used in the operating
10 suite, so is there a specialty that assumes primary
11 responsibility for those issues? Or is it the hospital that
12 does?

13 MR. GORDON: I don't know that we can say there's
14 a uniform practice. There are obviously hospitals have
15 purchasing departments and but specifically what's happening
16 in the OR, Dr. Mont at least has testified that as the
17 orthopedic surgeon, he is ultimately responsible for
18 everything that goes on in the OR and therefore has to be
19 aware of. You know, that being said, he doesn't literally
20 do everything in the OR. My partner, Deborah Lewis, former
21 OR nurse, I might add, is going to talk a little bit more
22 about some of the different roles of the charge nurse. The
23 anesthesiologist, that's typically the person in charge of
24 deciding what's going to be used for patient warming and
25 those sorts of things. And then there's a whole group of

1 people known as bio meds. They are the people who are
2 responsible for cleaning, maintaining, you know, and
3 sometimes purchasing the equipment in a hospital. I don't
4 know if that answers your question, but there are different
5 people, different disciplines, but ultimately when, you
6 know, the buck stops with the orthopedic surgeons for what's
7 going on in his or her operating room so --

8 JUDGE LEARY: Well, I'm not sure if that last
9 statement is true, at least my understanding, but I'm not
10 going to impose my understanding in terms of what the record
11 is in this case. But it seems to me that anesthesiology
12 might have something to say about the safety of the patient
13 given that it's the ASA number that is often crucial in
14 determining the condition of the patient for surgery.

15 MR. GORDON: Absolutely.

16 JUDGE LEARY: And the other part of it is that
17 Scott Augustine who designed the Bair Hugger as well as the
18 HotDog is my understanding is he's an anesthesiologist, so
19 at some point in time I'd like to hear a little bit more
20 about the dynamic for making decisions about what is
21 appropriate for a patient and recognizing the need for
22 patient safety in the operating room and whether or not it's
23 a collaborative decision or not and whether or not there's
24 anybody outside of -- I assume we would have heard it if it
25 was, but if there's anybody in the field of anesthesia or

1 anesthesiology that has looked at this issue or whether or
2 not hospitals internally take a look or collectively take a
3 look at these issues so.

4 MR. GORDON: And I think you will hear more about
5 that when we talk about their motion to exclude our
6 anesthesiology expert Dr. Hannenberg or from the OR Nurse
7 Hughes which can be handled by Ms. Lewis.

8 JUDGE LEARY: Thank you.

9 MR. GORDON: Thank you, Your Honor.

10 THE COURT: Thank you. Ms. Zimmerman, are you
11 going to talk to us about the Wenzel motion?

12 MS. ZIMMERMAN: Dr. Wenzel, yes, Your Honor.

13 THE COURT: Ms. Zimmerman, can I ask you a
14 question while that's getting set up?

15 MS. ZIMMERMAN: Certainly, Your Honor.

16 THE COURT: Are there studies that have been done
17 after the 2013 convention that are not publicly available?
18 Is the plaintiff relying on any studies that are not
19 publicly available?

20 MS. ZIMMERMAN: Well, we are relying on
21 Dr. Elgobashi's CFD test, and I think that that is certainly
22 something that was not available to the international
23 consensus.

24 THE COURT: Right. Is that publicly available
25 now?

1 MS. ZIMMERMAN: Well, it is now because it's been
2 publicly filed as exhibits to various motions here, but I
3 know that it's also been submitted for publication.

4 THE COURT: Okay. But the hospitals say the --
5 you know, there's some big hospital groups like, well,
6 what's the one in California?

7 MS. ZIMMERMAN: Kaiser?

8 THE COURT: Yeah, right, that have huge committees
9 that look at everything. Would those committees have access
10 to all of the information that you are relying on?

11 MS. ZIMMERMAN: That's a great question, Your
12 Honor. I think that, unfortunately, the answer is usually
13 no, they don't have access to internal documents, much like
14 the FDA usually doesn't have access to internal documents.

15 THE COURT: But the studies?

16 MS. ZIMMERMAN: Right. But so, for example, when
17 the international consensus meets and they review what's
18 available, first of all, we don't know everything that they
19 did have available to them. We know what they ultimately
20 concluded. But we know just since the time the
21 international consensus met, Darouiche is new, Stocks is
22 new.

23 THE COURT: But it's not private?

24 MS. ZIMMERMAN: It is not private.

25 THE COURT: There's some things that are sealed

1 here, and so I'm just asking about what is -- what's a
2 secret that wouldn't be publicly available to somebody who
3 had, you know, the time and resources to find it, but you're
4 not relying on secret studies.

5 MS. ZIMMERMAN: We don't have any secret studies
6 that we're relying on, and none of our experts do either.

7 THE COURT: Okay.

8 MS. ZIMMERMAN: But I think that your last question
9 goes really to the ability of any particular researcher
10 organization or expert on either side of the V to really sit
11 together and draw from the available, publicly available
12 information, confidential documents, testing done as part of
13 this litigation or prior to this litigation, to weave this
14 together to really draw out of those the meaningful answers
15 to the questions that are presented to this Court right now
16 and that is general causation, is the Bair Hugger machine
17 capable of depositing bacteria at the surgical site?

18 THE COURT: I guess that's kind of what -- that is
19 sort of what I'm asking, is that -- is there something that
20 the litigation process can provide that a medical researcher
21 or a hospital or somebody out in the non-courtroom world
22 couldn't do? Do orthopedists need us because we have access
23 to things that they don't have?

24 MS. ZIMMERMAN: I think that they do need us, Your
25 Honor. I think -- I harken back actually to a case I first

1 appeared in front Judge Leary in Guidant, and I think it is
2 illustrative of some of the questions that came up yesterday
3 with respect to the FDA and what is known. How did that --
4 how did Guidant come to be a recall? And I know this is a
5 little bit of aside, but if you'll indulge me for a minute,
6 Guidant became recalled, it was a defibrillator that had a
7 known defect. It came to be known because a lawyer in Texas
8 got a call from a family in North Dakota who had a 19-year
9 old kid who died, and he died because the defibrillator in
10 his heart had a defect. And this lawyer took it on and he
11 got the internal documents that were not available to the
12 FDA. He took depositions and he ultimately discovered and
13 proved that in fact this particular defect was known to the
14 company, that they fixed the defect, that they sent the new
15 machines out to the field, put them on the shelves, didn't
16 retract the old machines, kept them on the shelves so that
17 they couldn't be implanted in patients, but so -- and that's
18 what lead to the recall there.

19 THE COURT: Right, right. And there are lots of
20 examples where similar to that.

21 MS. ZIMMERMAN: Certainly, right.

22 THE COURT: But here's there's not an allegation
23 of a defect per se that wouldn't be known. The Guidant
24 defect, the -- I don't know, maybe it was in some on the
25 Stryker litigation, it was commonly you've got a defect that

1 doesn't come to light until that process.

2 MS. ZIMMERMAN: Until that extra study is done,
3 that's right.

4 THE COURT: But here, if you're relying on
5 publicly available studies, there's not a -- the aha that
6 can come from that process is -- it seems that it's -- it's
7 difference because it's substituting a judgment over the
8 same information that has been looked at and can be looked
9 at by people who are in the field.

10 MS. ZIMMERMAN: Well, respectfully, Your Honor, I
11 don't think that we know that it is the same information.
12 And at a minimum, what I would say is that none of these
13 organizations have had the CFD test that Dr. Elghobashi did
14 in this case. Now, could it have been done prior?
15 Possibly. It's an extraordinarily fact intensive,
16 technology intensive endeavor. And much like we see these
17 banners on the international consensus, these organizations,
18 they need sponsorship, whether from 3M or from Stryker or
19 from any kind of a company, apparently -- and sometimes it
20 comes up in litigation. But we don't have experts that
21 necessarily, even if they want to study something, they
22 don't have the 150, 250, 500 thousand dollars sponsoring the
23 study they want to do.

24 So what I think is important and I would submit to
25 the Court is important in looking at that international

1 consensus data and position is that they are saying we want
2 extra study, we want this done. And they didn't have, when
3 they issued these opinions in 2013, these widely held
4 consensus statements, they didn't have Darouiche talking
5 about the doubling of the risk of infection for every ten
6 colony forming units perimeter cubed over the surgical site.

7 And so what happens here, and we're going to try
8 to continue to tie this together for Your Honors throughout
9 the rest of today and how this is really an engineering
10 case, it's not a pharmacology case, but the engineering
11 really here explains the role of the machine in depositing
12 the known agent into the patient, and that's something that
13 was not available to the international consensus when they
14 made these proclamations. So we think that the
15 international consensus is reliable, but they didn't have a
16 full picture. I don't know what the FDA had. I don't think
17 they probably had Dr. Elghobashi's report, but we don't
18 know.

19 THE COURT: All right. Thank you very much.

20 MS. ZIMMERMAN: And I know that Your Honors want
21 to get through Wenzel pretty quickly so I'll try to do that.
22 Again, we don't dispute that Dr. Wenzel is a highly
23 qualified physician with expertise in infectious disease,
24 and he agrees with the plaintiffs and with, frankly, the
25 facts in many respects.

1 I wanted to put this up today because Your Honors
2 have had some questions throughout yesterday and today about
3 surgical site infection versus deep joint infection and
4 really what is what? Surgical site infection is the broad
5 category of infections that can happen during a surgery, and
6 this is a chart, by the way, that comes from Document 810-2,
7 it's also Defendant's Exhibit 47. It's from the CDC. And
8 it's a chart that shows the difference, and you'll see at
9 the top, there's superficial incisional SSI surgical site
10 infection. Those are the kinds of infections that require
11 tens of thousands of pathogens to be deposited to cause that
12 kind of infection. What we're talking about is the deep
13 incisional SSI that's also known as DJI, deep joint
14 infection, or PJI, periprosthetic joint infection.

15 And this also, same exhibit, Defendant's
16 Exhibit 47, and I know that the font is probably a little
17 bit small, but it does describe in hopefully helpful ways
18 for the Court the difference between superficial incisional
19 surgical site infection and deep incisional surgical site
20 infection, also known as deep joint or periprosthetic joint.

21 So again, Dr. Wenzel agrees, and this is an
22 undisputed fact, bacteria are the real crux of the issue
23 here, so it's not like *Glasstetter* or like many of the other
24 kinds of pharmacology cases that we might be talking about
25 if exposure to a particular agent going to be capable of

1 causing the kind of problems that the plaintiffs allege in
2 the case. Here's it's absolutely a question about the
3 bacteria getting into the incision during the surgery.
4 That's undisputed. The question is, how does it get there?

5 And this kind of goes to the vast majority,
6 frankly, of Dr. Wenzel's opinion which the plaintiffs
7 brought our motion to challenge Dr. Wenzel on Daubert
8 grounds largely because of the Court's scheduling order, and
9 we felt that we needed to bring Daubert motion now or feel
10 that they would be waived, but most of the opinions that he
11 offers in his report really have to do with case specific
12 issues that don't touch on general causation at this point.

13 Another thing that the plaintiffs agree with, with
14 respect to Dr. Wenzel, he says that infection rates are
15 going up, and that is in his report at 13. There is some
16 information from the CDC about how much they've been going
17 up. Significantly, thousands of additional infections.

18 THE COURT: Percentages going up, too?

19 MS. ZIMMERMAN: Yes. So there are more surgeries
20 and there are more infections but it's also a greater
21 percentage of the surgeries are happening.

22 JUDGE LEARY: So what do you -- what does
23 Dr. Wenzel glean from that?

24 MS. ZIMMERMAN: What does Dr. Wenzel glean from
25 that? What he says in his report is that essentially there

1 is a lot of people that are more compromised going into
2 surgery, and we disagree with that. We think that there --
3 because at the end of the day, whether somebody is obese or
4 a smoker or immuno compromised in any way, they don't
5 spontaneously come down with an infection unless they are
6 exposed to the bacteria, so that's the prerequisite for any
7 kind of an infection.

8 Now, it may well be that if the population as a
9 whole is not as well, as healthy, as fit for surgery that
10 they are less capable of fighting off these kinds of
11 bacterias, and so, I mean, certainly we all have bacteria,
12 probably we're all covered in it right now, it doesn't mean
13 you're going to come down with an infection all the time but
14 you may. So at any rate, the issue really is exposure to
15 the bacteria, particularly during the surgery while the
16 incision is open and these implants are being placed.

17 THE COURT: So weren't the implants sued? Are
18 those the Stryker lawsuits?

19 MS. ZIMMERMAN: There are certainly Stryker
20 lawsuits. There are a host of defective hip implants and
21 knee implants that have been used in the last many years.

22 THE COURT: You don't know whether any of those
23 defective implants were used in the McGovern population, do
24 you?

25 MS. ZIMMERMAN: I don't know that, Your Honor. I

1 know that one of the issues with respect to surgeries is
2 there are a greater proportion of revision surgeries over
3 the last 15 years, probably because, at least in part, due
4 to all the recalls that have happened, and there is a
5 greater incidence of infection during the revision surgery.
6 The thought process, according to Dr. Jarvis in his report,
7 really has to do with it's a longer surgery, and it would be
8 consistent with the plaintiffs' theory that they're exposed
9 to air that is turned up by the Bair Hugger for a much
10 longer period of time and they're more likely to come down
11 with an infection then.

12 THE COURT: All right.

13 MS. ZIMMERMAN: So Dr. Wenzel agrees that as long
14 as there is proper skin antisepsis that is presumed to
15 destroy all viable bacteria on the patient's skin, and
16 that's at his deposition page 204, line 6. It's Exhibit A.

17 Counsel for 3M in their -- excuse me, in their
18 response to the motion on Dr. Wenzel, they say the fact that
19 no other equipment in the operating room has not been
20 studied, is believed to pose no risk and is of no
21 consequence. So there's a lot of hay to be made in
22 Dr. Mont's report and in Dr. Wenzel's report about all of
23 these machines that might be causing infection. And at
24 their deposition and in our motions, we say what are you
25 relying upon for that? And the response is, well, you know,

1 there's not a lot of study on that.

2 Most importantly, I think, Dr. Wenzel at his
3 deposition testified that perhaps 40 percent of operating
4 room particles carry bacteria. Why does that matter? Well,
5 it matters, Your Honors, because the testimony in this case
6 and the admissions from 3M is that use of the Bair Hugger
7 causes increased particles, no matter the study, plaintiffs'
8 study, internal study, external independent study, they all
9 show more particles.

10 And I'm just going to jump ahead really quickly
11 and try to be mindful of the Courts' time. Dr. Wenzel
12 attaches at the end back of his report starting at page 75,
13 discussion about the applicability of the heater-cooler, and
14 Your Honors may remember this because there was some
15 discussion of it at science day. And this was another,
16 frankly, that was not before the international consensus
17 when they made their proclamation with forced-air warming.

18 Why does it matter? Well, first of all, this
19 involved a heater-cooler unit which is pictured on the left.
20 It looks a little bit like the Bair Hugger, but they serve
21 different purposes, and we would not represent to the Court
22 they're absolutely equivalent. The thing that's important
23 about the multiple studies that happened in the
24 heater-cooler unit that Dr. Wenzel discounts entirely is
25 that the authors of the heater-coolers unit studies, and

1 they're multiple, they find that that particular device is a
2 reservoir of infection, of colony-forming units and bacteria
3 in the operating room. And what happened there -- and it
4 was contaminated at the source where they made it. I don't
5 think that that's relevant to the issue before this Court.
6 The question in heater-cooler was if you have a machine
7 sitting in the OR and it's got germs in it, pathogens,
8 bacteria, and they demonstrate that those bacteria can be
9 aerosolized, they can move through the air, and they deposit
10 themselves in the surgical site and cause an infection, so
11 that's a mechanism of injury, that's what they showed in the
12 heater-cooler case, and then ultimately through the course
13 of a number of different studies led to the recall of these
14 particular devices.

15 The only reason that the authors were able to
16 learn about that was because it was such a rare bacteria,
17 mycobacterium chimaera. And so when Dr. Jarvis talked about
18 it at science day and when he talks about at his deposition
19 and his report, he talks about really as a canary in a coal
20 mine, that if it hadn't been such a bizarre pathogen that's
21 normally found in your lungs, kind of like tuberculosis, or
22 they found it in heart tissue in a couple of different heart
23 surgery patients that have been the same hospital a couple
24 years apart, if they didn't see that, if it wasn't so rare,
25 they wouldn't have known to study it. And that mechanism of

1 aerosolized bacteria coming from hospital equipment to a
2 patient surgical site was information that was not before
3 the international consensus back in 2013 because it wasn't
4 known yet. So it's incredibly relevant, despite
5 Dr. Wenzel's disregard of it. One of the studies used smoke
6 studies in understanding the mechanism of transport from the
7 heater-cooler unit in the operating room to the surgical
8 site.

9 And then, just finally, we would say that with
10 respect to Dr. Wenzel, he's certainly qualified on issues
11 with respect to infectious disease, but his qualifications
12 do have limits. Plaintiffs will rest on their papers with
13 respect to his expertise in the areas of normothermia and
14 computational fluid dynamics and engineering. If Your
15 Honors have any questions? I'll sit down.

16 JUDGE LEARY: Thank you.

17 THE COURT: Thank you.

18 MAGISTRATE JUDGE NOEL: No offense to anybody, I'm
19 leaving to do criminal duty stuff. I know I got mocked
20 yesterday so.

21 THE COURT: Did you?

22 MAGISTRATE JUDGE NOEL: You mocked me.

23 THE COURT: What did I say?

24 MAGISTRATE JUDGE NOEL: I don't remember.

25 THE COURT: It was cruel.

1 MAGISTRATE JUDGE NOEL: No, it was all in good
2 fun.

3 THE COURT: Ms. Young.

4 MS. YOUNG: Good morning, Your Honors, counsel.
5 Dr. Wenzel has a 75-page report in which he carefully
6 analyzes all of the science that would relate to the
7 interrelated topics at issue here, when we're looking at not
8 only whether the Bair Hugger is capable of causing surgical
9 site infections but what the other potential causes might
10 be, and Your Honors have asked a number of questions about
11 confounders, risk factors. Dr. Wenzel has detailed the
12 research across all of those subjects in his report.

13 There's been a lot of discussion about PJI versus
14 SSI. Based on the information that Ms. Zimmerman just
15 presented it's clear that PJI is a subset of an SSI, and if
16 you look at the research, they don't always distinguish
17 between the two. And we submit, again, the issue has been
18 addressed within the context of PJI's and there's no
19 distinction that matters for the purposes of the discussion
20 here today.

21 What Dr. Wenzel also concludes based on the body
22 of scientific evidence, so he's looking at the RCTs, he's
23 looking at the biological plausibility research, he's
24 looking at experimental or theoretical research, and he's
25 looking at the epidemiology. He has concluded not only that

1 the Bair Hugger is not capable of causing a periprosthetic
2 or prosthetic joint infection but, in fact, the opposite is
3 true. It is both safe and effective, including for patients
4 undergoing total hip and total knee arthroplasty procedures.

5 And the research that he looked at is not only
6 across all of these interrelated fields, but he's also
7 looked at the evidence in this case and so he's looked at
8 the information that was discovered in the UK, some of the
9 analysis that was done after the data was made available for
10 the McGovern study, and so he is the person who has done the
11 full research on the issues that matter to this Court.

12 He also has a very succinct discussion of McGovern
13 beginning at page 62 of his report. And what he points out
14 at the very beginning of his opinion, which Your Honor
15 picked up on this yesterday, was that while that study may
16 on its face show an association, that association is not
17 causal as related to the Bair Hugger because of all of the
18 things that we've talked about, about the confounders, about
19 the not being controlled, about the co-morbidities being one
20 of them that were not controlled. And he also talks about
21 the study having bias, systemic bias that couldn't be
22 controlled, and so Your Honors I think will find that quite
23 succinct discussion at page 62 to 68 of his report, as well
24 as answers to questions about what does the skin prep
25 matter, how do we know that the skin is the primary source

1 of the bacteria that leads to surgical site infections, and
2 he analyzes the science on the p-acnes, which is a
3 particular type of bacteria found only on the shoulder, and
4 how that particular bacterium is responsible for shoulder
5 prosthetic joint infections, not knee and hips. So he has
6 -- his report I think will be very useful to the Courts in
7 those regards.

8 Very briefly, I think plaintiffs' characterization
9 that Dr. Wenzel agrees that it's bacteria that causes
10 surgical site infections is gross oversimplification of the
11 scientific issues here. Of course it's the bacteria that
12 causes the surgical site infection, but how does that
13 bacteria get into the wound, and what Dr. Wenzel's analysis
14 has shown is that it's primarily from the skin. You can
15 prep the skin, you can never make it sterile, and you
16 certainly can't -- remove the bacteria that's below --
17 that's in the patient as well. So Dr. Wenzel details all of
18 those items.

19 And he also talks about risk factors as being
20 causal. There's been a lot of discussion about it's not
21 risk factors that cause infection, it's bacteria that causes
22 infection. And in his deposition, he simply said to
23 plaintiffs' counsel, you and I are just going to disagree on
24 that. I mean, I think that risk factors are by definition
25 causal. And you can find his testimony related to that

1 topic at page 276.

2 With respect to the heater-cooler unit, as we
3 talked about at science day, that involved a very particular
4 type of bacterium that was then linked to a cluster of
5 infections. It's not on point and does not support
6 plaintiffs' position that the Bair Hugger has been --
7 there's any scientifically valid that the Bair Hugger is
8 capable of causing infections.

9 And with that, Your Honor, I will rest on our
10 papers.

11 THE COURT: Thank you, Ms. Young.

12 JUDGE LEARY: Thank you.

13 THE COURT: All right. Can we talk about Hughes
14 -- or Hannenberg and Huguhe, in whatever order you'd like
15 to address them? Ms. Zimmerman, is that you?

16 MS. ZIMMERMAN: Does the Court wish to hear from
17 us?

18 THE COURT: Or if you want to save your time and
19 move right to engineering.

20 MS. ZIMMERMAN: With respect to both Hannenberg
21 and Hughes, particularly on the issue of general causation,
22 it's the plaintiffs' perspective -- defendants have not
23 offered Ms. Hughes in particular to opine in any way on the
24 safety or efficacy of the Bair Hugger. We think that any
25 opinions that she might be qualified to offer would not be

1 relevant to this stage of the proceedings, and we would rest
2 on our papers in that regard.

3 Similarly, with respect to Dr. Hannenberg, he's an
4 anesthesiologist with some experience in using the Bair
5 Hugger in practice. The plaintiffs' position is that the
6 vast majority of the testimony and opinions offered by
7 Dr. Hannenberg would also really go to specific causation.
8 And we are happy to rest on our papers and take the extra
9 time with our engineers.

10 THE COURT: Thank you. Thank you very much for
11 that.

12 Mr. Blackwell, anything from your side on those?

13 MR. BLACKWELL: Just one moment, Your Honor.
14 Maybe not.

15 Your Honor, we'll briefly make a couple of points
16 on Hannenberg and the engineers.

17 THE COURT: All right. Ms. Lewis.

18 MS. LEWIS: Good morning, Your Honors. Deborah
19 Lewis. I would like to, before I start, clear something for
20 the record that was discussed yesterday. I think it was
21 Judge Noel who asked the question whether all the cases in
22 the MDL were orthopedic cases, and I don't remember which
23 counsel said yes, they were, but that is not the case. We
24 certainly keep track of all the different types of
25 surgeries, and there are abdominal surgeries that have been

1 filed, neuro surgeries that have been filed, cardiac
2 surgeries filed, cases concerning the muscles and tendons,
3 and the good majority of cases are ortho cases, but for all
4 the ortho cases, all of them aren't involving prostheses and
5 all the patients aren't claiming deep joint infections.
6 There are many cases where they're just claiming a skin
7 infection called cellulitis.

8 THE COURT: I think for the bellwethers we
9 isolated --

10 MS. LEWIS: That's right.

11 THE COURT: Okay. Thank you.

12 MS. LEWIS: But that was to clarify. And
13 Mr. Sacchet said today that was the reason we brought all
14 these cases, you know, for ortho case, and, again, we just
15 wanted to clarify for the record there are all sorts of
16 cases being filed.

17 Defendants are asking this Court to deny
18 plaintiffs' motion to exclude the expert opinions of
19 Dr. Alexander Hannenberg who is a Board certified
20 anesthesiologist. Dr. Hannenberg's opinions on the safety
21 and effectiveness of the Bair Hugger are relevant, reliable,
22 and are based on reliable scientifically valid evidence.

23 Patients, at least in their papers, challenge
24 Dr. Hannenberg's qualifications, but as evident in both his
25 report and in his CV which is attached to his report and are

1 in the record, his qualifications to offer opinions on
2 normothermia, hypothermia, infection measures employed
3 during surgery, and the safety and effectiveness of the Bair
4 Hugger system are without question and are more than
5 sufficient.

6 He is, as we mentioned in our papers, the only
7 anesthesiologist who's been designated by either party as an
8 expert witness. That means he's the only medical physician
9 who has actually used the Bair Hugger system. So he will
10 certainly be important to the trier of fact to discuss how
11 it's used, how anesthesiologists use it, why they use it,
12 why it's his opinion, and others. The American Society of
13 Anesthesiologists endorses forced-air warming, so he's able
14 to explain to the jury his opinion on the safety and
15 effectiveness of it, and that, to a good part, is also based
16 on his experience, but these are things that he can talk
17 about.

18 Also, as noted in our papers, Dr. Hannenberg has
19 over 30 years as an anesthesiologist and over 20-something
20 years using the Bair Hugger system on a daily basis.

21 Dr. Hannenberg has published. It's an editorial
22 that he published in 2008. It was titled Improving
23 Perioperative Temperature Management. It was in the
24 International Anesthesia Research Society. It's listed in
25 his CV in which he talked about in that editorial the

1 studies that were germane to the risks of hypo -- that dealt
2 with the risks of hypothermia, including the risk of
3 surgical wound infection with hypothermia. He talked about
4 the benefits of normothermia and the safety of patient
5 warming systems.

6 Dr. Hannenberg also has been instrumental in
7 developing the performance measures for temperature
8 management by anesthesiologists, and that involves, of
9 course, in treating hypothermia and in maintaining
10 normothermia during the operative procedure.

11 According to Dr. Hannenberg, he said that the Bair
12 Hugger has been part of this strategy to reduce the
13 likelihood of surgical site infections in his practice.

14 With respect to infection prevention issues, he
15 discuss in his report how anesthesiologists are even
16 involved in infection mitigation, something people may not
17 think about from what the anesthesiologists do, but they
18 actually help to mitigate risks. They, as he mentions in
19 his report, and we know that the one thing that they use, of
20 course, is thermoregulatory systems, patient warming
21 devices, that's one thing they do, but he also mentions that
22 they control, help control blood glucose levels during the
23 surgery because that can have an effect on whether a patient
24 develops an infection, and they also are measured in when
25 they give antibiotics during surgery. There is a specific

1 time when it's best to give the antibiotic and then if the
2 surgery is too prolonged, they might give an additional
3 dose, but those are things in which anesthesiologists do in
4 order to help reduce surgical site infections.

5 The scientific studies that are the subjects --
6 that include subjects on hypothermia and normothermia and
7 infection prevention are the very types of studies that
8 Dr. Hannenberg knows about, routinely reviews, and they help
9 him make decisions, clinical decisions on the treatment of
10 patients during general surgery. I won't go anymore into
11 detail about his qualifications because I think it's fairly
12 obvious not only from his report but from his CV as well.

13 With respect to what process he undertook to make
14 his decisions, I think also his report is relatively clear
15 on what he did. He knows, again, about the Kurz study that
16 we talked about yesterday which is one of the RCTs that
17 involves colorectal surgery. According to Dr. Hannenberg,
18 it doesn't make a difference that it was colorectal surgery,
19 and he says in his report the reason why is because it's a
20 physiology question. In other words what happens when we
21 get cold? We have vasoconstriction. What happens when our
22 blood vessels vasoconstrict? That means that the white
23 blood cells can't get to certain tissue, and so that -- and
24 he says it doesn't make a difference, that same thing is
25 going to happen in our body no matter whether it's a hernia,

1 no matter whether it's a orthopedic procedure, no matter
2 whether it's a neuro surgery. Vasoconstriction is
3 vasoconstriction.

4 And he's not the only one who thinks that as well.
5 That is the consensus of other studies that -- and even as
6 counsel brought up today showing you the ICM and what they
7 said about that in which it said we support the general
8 recommendations from general surgery. So the orthopedic
9 community is not saying not to warm patients.

10 Just briefly, again, on the other things that he
11 undertook, he looked at, again, the Kurz study, he knew
12 about that study, knew about the Melling study. The Melling
13 study, although it's prewarming, according to Dr. Hannenberg
14 and what he said during his deposition is what matters, is
15 that patients were warmed and the effect from the Melling
16 study that showed the benefits of warming to patients.
17 Melling I think was involving several different types of
18 surgeries.

19 There is another -- there is a study in 2016 on
20 fracture patients that Dr. Hannenberg also cites that also
21 showed benefits from warming patients. We talked about the
22 evidence that he looked at that study as well. But, again,
23 all of the things that he did and undertook are contained
24 within the record at DX1, page 26 is his materials
25 considered list.

1 I will say the last thing with respect to whether
2 this is accepted within the general community,
3 Dr. Hannenberg supplemented his expert report, that is part
4 of the record as well at 869-1, page 28, in which he says
5 the FDA's letter to professionals is a letter that would be
6 addressed to him because, again, he is the one who makes
7 decisions on whether to use the Bair Hugger system or not.

8 And he says that the FDA letter also supports his
9 conclusions reached that the Bair Hugger should be continued
10 to be used, the Bair -- his opinion that the Bair Hugger is
11 safe and effective, and he also says, and I will just quote,
12 This information from the nation's authority on the safety
13 of medical devices further underscores the validity of the
14 conclusions I presented in my earlier letter.

15 Lastly, Dr. Hannenberg does offer an opinion on
16 labelling and warning, and as he mentions in his report and
17 as evident in the *In Re Mirena* IED product liability case,
18 he again is the end user to whom that warning, if warning
19 was needed, would be addressed, so he is certainly qualified
20 to say whether there is a warning necessary, and it's his
21 opinion, as noted in his report, that no warning was
22 necessary because there was no credible evidence of an
23 increased risk of surgical site infections.

24 And I think that based on that, if no questions,
25 we'll rest on our papers.

1 THE COURT: All right. Thank you, Ms. Lewis.

2 All right. Now I think the next thing on the
3 schedule that we sent out would be defendant's motion to
4 exclude Elghobashi.

5 MR. ASSAAD: I think it was to all the engineering
6 experts.

7 THE COURT: Oh, yeah, Elghobashi, Buck,
8 Koeningshofer, and David.

9 MR. GOSS: That's right, Your Honor. That's
10 right. May it please the Court, my name is Peter Goss.
11 It's my privilege to be here today representing 3M.
12 Counsel. And I'm going to be discussing -- how do I lower
13 this? Or can I?

14 THE COURT: There you go.

15 MR. GOSS: There we go. It's a little more
16 comfortable this way. Do you have my presentation up?
17 Okay. Great.

18 All right. So as the Court noted, I'm here to
19 address the motion on the plaintiffs' engineering experts.
20 There's Daniel Koeningshofer who is an HVAC heating,
21 ventilation, air conditioning engineer who works with
22 hospitals. There is Dr. Said Elghobashi who is an expert in
23 computational fluid dynamics. There is Dr. Yadin David who
24 is a biomedical engineer. You're going to be hearing about
25 him on regulatory issues later, but he does have a couple of

1 opinions that relate to this portion of the case. And then,
2 finally, there's Michael Buck who did an engineering type
3 study in support of plaintiffs' arguments in this case.

4 But I want to come back to the framework that
5 Mr. Blackwell laid out yesterday for how to analyze issues
6 of medical causation, and what I'm going to be talking about
7 today is really on the left-hand side of the screen in the
8 realm of the experimental and theoretical and the realm of
9 the biological plausible. And I just want to be clear that
10 those things combined are not enough under the case law to
11 get you to an association that will get you to causation.
12 So within the realm of the experimental and theoretical, the
13 plaintiffs are relying on particle testing, which we've
14 heard a lot about, their litigation CFD, and then there are
15 eight studies that were instigated by Dr. Augustine that
16 concern bacteria, particles, and airflow.

17 We've already many times discussed the fact that
18 there is no biological plausibility study from the
19 standpoint of actually measuring bacteria coming out of the
20 Bair Hugger or bacterial increases in the operating room
21 that can be attributable Bair Hugger operation, and that's
22 been studied many times, and no clinically meaningful
23 increase in bacteria has been found, no bacteria has been
24 found coming out of the Bair Hugger blanket when it's used
25 as it's intended.

1 So, again, I am focused purely in this area on the
2 far left, the experimental and the theoretical, which is
3 never going to be enough to get you over the troubled waters
4 of the joiner gap, which is depicted right here, before you
5 get to the gold standard proof of causation.

6 The exploratory studies, again, from the far left
7 side of the graph here, those were all connected to
8 Dr. Augustine and his employee Mark Albrecht, and it's
9 detailed in our motion how those are connected. I'm not
10 going to go through that here. Just suffice to say that all
11 of these exploratory studies ultimately trace their origins
12 to Augustine by medical and design.

13 And Dr. Augustine has promoted two theories of
14 causation, two theories for how the Bair Hugger could cause
15 a surgical infection. One, you just heard counsel use the
16 reservoir of infection. This is --

17 THE COURT: One it blows infection that's in the
18 thing, the other is it stirs up stuff that's on the floor?

19 MR. GOSS: Yep, exactly right. So this is the
20 reservoirs of infection brochure that he handed out at
21 American Society of Anesthesiology conference. It says
22 contaminated air is blowing from the unit. Particle
23 counters have measured more than 50 million germ-sized
24 particles. And what are these 50 million particles? Well,
25 not all of the particles are bacteria but bacteria can be

1 cultured from both the air and hoses of any many hot air
2 warming units. That's actually not true. Dr. Augustine and
3 Mark Albrecht tried to culture bacteria from the air of a
4 Bair Hugger system and they failed, so I'm going to talk
5 about that a little bit later.

6 The next theory is this air flow disruption theory
7 where waste heat from the Bair Hugger comes from under the
8 drapes and rises up over the patient and dumps particles
9 containing bacteria into the surgical site. I think we
10 heard the term that the Bair Hugger churns up the air in the
11 operating room, so that's the other theory. And those are
12 Augustine's theories, and plaintiffs have adopted them, and
13 so have their experts.

14 And the eight studies break down according to two
15 basic groupings that align with those theories. They are
16 the three crud and bug studies where Albrecht went to
17 different hospitals and said, hey, we can swab bacteria out
18 of the hoses and out of the warming units and we can count
19 particles. And so if we publish that, we'll get people to
20 think, aha, there are particles coming out, there are bugs
21 on the surfaces, the particles must be bacteria, but the
22 part that they didn't tell you was that they actually tried
23 to find the bacteria and they got none.

24 And then there are a five air flow disruption
25 studies. The McGovern 2011 study actually began life as an

1 air flow disruption study, only later did they say, hey, we
2 you know, made the switch to HotDog, let's look at our
3 infection rate and see if we can make something of that. So
4 it actually started out as one as one of these mechanistic
5 studies and only later became an observational study.

6 And those five air flow disruption studies used
7 bubbles, tracer particles, trace smoke to try to say that
8 this Bair Hugger system is churning the air in the operating
9 room which is a potential mechanism for infection.

10 This is just some shorthand for the plaintiffs'
11 experts actually espousing those theories. So in the
12 reservoirs of infection, you have Mr. Koeningshofer saying
13 that the Bair Hugger draws particles off the floor into the
14 unit. Dr. David says the Bair Hugger harbors bacterial
15 growth. Mr. Buck says the Bair Hugger causes increase in
16 the number of particles in the operating room. So that's
17 kind of in the reservoir of infection rubric.

18 For air flow disruption, you have Koeningshofer
19 saying the hot air from the Bair Hugger will interfere with
20 the downward flow of clean air from the ceiling diffuser.
21 And Dr. Elghobashi, of course, says based on the model that
22 he outsourced to one of his colleges, Dr. Abdi, the air flow
23 will be disrupted around the operating room table.

24 So the plaintiffs have adopted these theories that
25 were brought to life by Dr. Augustine, but they're theories.

1 And what numerous cases have held is that causation in a
2 medical tort case like this one has to be based on more than
3 a possibility. And how do you get from possibility to
4 something that the Court can rely on in saying there's
5 enough here to go to a jury? Well, there has to be testing.
6 And that's what Daubert said. Daubert said, Ordinarily, a
7 key can question to be answered in determining whether a
8 theory or technique is scientific knowledge that will assist
9 the trier of fact is whether it can be and has been tested.

10 So it's not just is it testable, is it falsifiable
11 but has it actually been tested? And there are a number of
12 cases that say you have to have testing in order to bring
13 that theory out of the realm of the possible and into
14 something that could be used to support a finding of
15 causation.

16 The *Polski* case from the Eighth Circuit is one
17 where a cough-cold treatment using zinc was accused of
18 causing the plaintiffs to lose their taste, their sense of
19 taste. And the Court said that the plaintiffs' experts
20 relied on an unproven and indeed untested premise.

21 The *Worth* case is another example where the
22 plaintiffs did a lot of testing they had a lot of ideas
23 about what could have caused, this is actually a very tragic
24 case involving an infant who was burned in a baby bassinet,
25 and they had lots of theories about how this fire could have

1 started but they didn't test the one theory that they said
2 was what actually happened in the case, and so the Court
3 said, well, if you didn't test it, we're not going to admit
4 it.

5 So has there been testing of this idea that the
6 Bair Hugger emits or increases bacteria? Yes, there has
7 been that testing for nine studies, published studies, over
8 25 years, that question has been tested and the answer has
9 been uniformly no.

10 And I understand Moretti came up again this
11 morning. Mr. Gordon may have addressed this earlier, but I
12 just want to come back to what the results were of Moretti.
13 This is Figure 2 from Moretti that shows the results of the
14 bacterial sampling that was done in the operating rooms in
15 this study. And, of course, there's at rest is what the
16 plaintiffs focus on, but here is the level of bacteria
17 during operations without the Bair Hugger, and here is the
18 level of bacteria during operations with the Bair Hugger.
19 And we're here to talk about surgeries in operating rooms
20 with people in there being operated on. We're not talking
21 about a room with nobody in it. We're talking about
22 surgeries that are taking place with people who bring their
23 bacteria to the surgery, whether it's the patient or the
24 staff or both.

25 THE COURT: Okay. So I see it says operational

1 with no forced air warmer.

2 MR. GOSS: Right.

3 THE COURT: Is that -- I think maybe --

4 JUDGE LEARY: Operational with forced air warmer.

5 THE COURT: No, this one.

6 JUDGE LEARY: Oh, I'm sorry.

7 THE COURT: I think Mr. Assad was saying that that
8 is a measurement while the nurses and everybody is in there
9 getting the patient ready but then there's a drop
10 afterwards, but is this -- what does this say about whether
11 that high number is when the nurses are and everybody is --

12 MR. GOSS: I don't think the study is clear what
13 happens during the operational period. I mean, it --

14 THE COURT: When it says operational, what does
15 that mean?

16 MR. GOSS: During the operation, that's what I
17 take that to mean, during operations. So regardless, the
18 conclusion of the study is what the Bair Hugger does not
19 increase the risk of nosocomial infections so that's
20 Moretti.

21 Let's see, I need to clear it.

22 THE COURT: I can do it. Don't worry about it.

23 MR. GOSS: Oh, thank you. There we go. Thank
24 you.

25 So the secret study is done by Mark Albrecht and

1 at the behest of Scott Augustine. The reason we call them
2 secret studies is that they bear directly on the papers that
3 were later published on this question of does the Bair
4 Hugger increase bacteria in the operating room, but these
5 studies were never disclosed. It's work that is directly
6 relevant to the issue that was never disclosed in the
7 studies they published later.

8 So just coming back to this, there were four
9 hospitals that Albrecht went to, to look at Bair Hugger
10 devices, and he sampled four bacteria using agar plates
11 which we've heard about. I checked last night on Amazon.
12 You can get ten of these for \$16.80, so it's an inexpensive
13 way to measure bacteria, and it's commonly done.

14 Now, Albrecht went a little bit beyond just using
15 agar plates to measure bacteria in these hospitals where he
16 did his studies. He actually used something called the
17 Anderson N6 impactor. I've got part of it highlighted here.
18 And here's a picture of that device. And what it is, it's a
19 pump that takes air either from the ambient operating room
20 or from the Bair Hugger machine from the end of the hose and
21 it pumps that air and impacts it using this device here onto
22 one of plates. So you put a plate in there and then it
23 captures the air and literally injects it onto the plate.
24 So you make sure that you're getting a very good sample of
25 wherever it is you're trying to sample.

1 All right. And let's see, what I need to show --
2 I don't know if you can do this, Brett, can you move this
3 out of the way? That was meant to be animated. This is a
4 table of the results that he got with the sampler. Thank
5 you. And the table on the left or the column on the left is
6 his impaction results. And on the left you'll see he says,
7 distal hose end, distal hose end, ventilation. And on the
8 far right where I have it highlighted it says CFU. And you
9 can see that he's got zeros for distal hose end and for
10 ventilation.

11 Now, the one place of interest is operating room 3
12 where he's got seven there, and what he says in his report
13 is, as a note, we intended to sample all of the ORs at rest
14 but OR3 in Regina had personnel traffic pass through the
15 room while the sampler was running. Well, that explains how
16 you get 7 CFUs. There were people in there. But otherwise
17 he got zero. That's the results of his testing, using not
18 just a passive bacterial agar plate but a machine that's
19 actually designed to inject the air onto it.

20 So the results of that work that he did was he
21 found no difference in bacteria counts with the Bair Hugger
22 on or off in the operating room and no bacteria in the air
23 coming out of the hose.

24 And I want to come back to Oguz because that's the
25 most recent example of a published study comparing bacterial

1 deposition rates between Bair Hugger and a convection device
2 that does not blow air -- I'm sorry, conductive device that
3 does not blow air and that's the HotDog. And there may have
4 been some question about whether any of the authors were --
5 had an association of some sort with the parties in the
6 litigation.

7 Oliver Kimberger is a researcher that 3M has
8 retained to do work in the past, but he's also done work for
9 Dr. Augustine. And in fact, he was a co-author on the Reed
10 crud and bug paper from 2013. This is what Albrecht
11 referred to as the European crud and bug paper. He a crud
12 and bug paper in Minnesota where they went to Minnesota
13 hospitals and they said, well, we swabbed bacteria out of
14 devices and we blew particles out of them; therefore,
15 conclude what you will, there must be bacteria coming out of
16 the device. Never mind the fact that he tested and didn't
17 find any. So Kimberger is the co-author on the study that
18 was done in Europe at Kimberger's hospital in Vienna. And
19 so they finally published this study in 2013.

20 But back in 2011 they were still working on the
21 manuscript, and Mark Albrecht wrote an e-mail to
22 Dr. Kimberger, and he said, "Say Oliver, would you able to
23 do me a small favor? I'm hoping you could go through the
24 attached manuscript and identify what needs to be removed to
25 get rid of the agenda, all of us at the company here are too

1 close to this and are not being objective as to what the
2 data supports, we would be really appreciative of any advice
3 you can offer." So Dr. Kimberger writes back, and he says,
4 "Dear, Mark. I will try sanitizing the manuscript in the
5 next week. Best regards, Oliver." So this is someone who
6 has a connection to the issues. He's certainly in this case
7 not a friend to 3M's side of it. He's aligned with
8 Dr. Augustine and he's helping Mark Albrecht.

9 Now, this is the page from the Oguz paper that has
10 the diagram of the placement of the different plates, and
11 plate 4 is the one that's arguably closer to the surgical
12 site. And there was a lot quoted from Oguz yesterday, and I
13 wanted to give the Court the full quote. So first they
14 start out by saying, In our study it was not possible to
15 detect any higher bacterial counts on any plates. So there
16 are all of these plates, and they said any plate. In the
17 forced-air warming group verses the resistive warming group.
18 True, the study may not obviously -- or may obviously not be
19 generalized for an overall safety statement on forced-air
20 warming and is primarily applicable in a particular surgical
21 setup, so that's the limitation of the study.

22 But they go on. However, with class action
23 lawsuits, judging the scientific question of forced-air
24 safety with unsuitable, i.e. legal means, subsequent studies
25 are all the more warranted. Only a large randomized

1 controlled trial of forced-air warming versus non-forced-air
2 warming will help to decide if patient outcome is influenced
3 by the use of forced-air devices. Until this study has been
4 performed, the hypothesized risks of forced air warming
5 remain unclear. With a multitude of factors influencing a
6 patients risk for perioperative infection, only this kind of
7 a study will be able to answer the question if forced-air
8 warming is a major influence on surgical wound contamination
9 whose voice can be reliably detected in the large choir of
10 all the other factors, like you heard about from Dr. Wenzel
11 and Dr. Hannenberg. The large choir of all the other
12 factors that are associated with surgical infection.

13 So Oguz is who's not lawyer basically reiterated
14 the framework that we laid out, that Mr. Blackwell laid out
15 at the beginning, that if you're really going to answer the
16 question, you need to have an RCT, if you're going to answer
17 the question scientifically. Short of that, all you have is
18 theory and the need for more study.

19 So what testing have plaintiffs' engineers done?
20 I heard the CFD referred to as a test. Respectfully, it's
21 not a test. It's a simulation. It's a computer similar
22 based on certain inputs. And in fact, the inputs as I'm
23 going to explain, were not validated and are not supported
24 by actual real world measurements. But first I want to talk
25 about particles. The plaintiffs retained Mr. Buck at the

1 University of Minnesota to do a particle counting
2 experiment. And so he took a Bair Hugger device into a
3 clean room over at the Department of Environment Health
4 where he works, and he hooked it up to a particle counter.
5 That's this device right here. And it has a probe. I think
6 you can kind of see right there. And he's counting
7 particles that are coming out of the hose.

8 All right. And then after he did that experiment
9 he wanted to see, well, what's coming out of the blanket?
10 So then he set up the Bair Hugger, attached it to a blanket
11 and he put the blanket in this Rubbermaid tub and he put the
12 particle counter and the probe inside the tub to see what
13 particle counts he would get coming out of the blanket. So
14 those were the two groups of experiments that he did.

15 He didn't look for bacteria. Were you asked to do
16 an evaluation of bacteria counting as part of your testing?
17 No. And, you know, as I pointed out, these agar plates are
18 not expensive. And Mr. Buck testified that he's actually in
19 charge of the micro lab for his department at the
20 University, so one would think it would be a fairly simple
21 plate to put in an agar plate in the Rubbermaid tub or in
22 the clean room, take it to the micro lab and see what you
23 get, but that was not done.

24 He used the particle counter. And what the Court
25 can see from this picture is the particle counter actually

1 breaks down the particles according to different sizes. And
2 that's really important because we know that certain
3 particles are too small to carry bacteria. This actually
4 shows a fairly typical distribution of particle counts
5 within a room. There will be a very large number of very
6 small particles, and that's just airborne dust. Very small
7 particles. And you'll have hundreds of thousand of those
8 particles in any given sample. But you'll have fewer
9 particles that are -- fewer of the larger particles, those
10 will tend to settle out, and so a typical reading from a
11 particle counter will look a lot like this.

12 And so these are some of Mr. Buck's results from
13 the test inside a clean room. And at the beginning of the
14 experiment, he turned the Bair Hugger on. And you can see
15 he gets these spikes in particles, large numbers of
16 particles, but if you take out the particles that are too
17 small to be bacteria or to carry bacteria, you get a very
18 different picture.

19 And this is just a quote from the plaintiffs'
20 brief in opposition. They say, Everyone in this case agrees
21 that at least 10 micron size particles can carry CFUs. We
22 agree that 10 micron particles can carry CFUs. Are -- we
23 have the only microbiologist in this case, it's Dr. Jim Ho,
24 he actually says particles as small as two and a half
25 microns can carry bacteria, smaller than that is too small,

1 they won't be carrying viable bacteria.

2 So if you look at Mr. Buck's results after you get
3 rid of the particles that are too small to be bacteria, too
4 small to carry bacteria, this is what it looks like. You
5 get a small number of bacteria in the two to five micron
6 range, slightly more in the five to ten micron range, and
7 very few in the greater than ten micron range which is kind
8 of the sweet spot for the plaintiffs that they've
9 identified.

10 And if you look, this orange bar for those greater
11 than ten micron particles, where you see them is at the
12 beginning and the end of the experiment, and that's not a
13 coincidence because what -- the way that Mr. Buck and his
14 colleague did the experiment, they would actually walk into
15 the room, turn the machine on and then walk into the room at
16 the end and turn it off. And so Mr. Buck said at his
17 deposition, So putting in the blanket into the container,
18 did that generate particles? Well, I don't want if it did
19 or not. Probably did. Well, we could have put particles in
20 the container as we were putting the Bair Hugger in there or
21 the blanket in there, that's a possibility. Isn't it a
22 probability? Well, it could be a probability, yes. So they
23 weren't wearing gloves, they weren't in containment suits,
24 they just walked into the room, turned it on and then turned
25 it off, so the higher readings at the beginning and end are

1 not a coincidence.

2 So there are a lot of these studies, the Augustine
3 studies, that have looked at particle counts. And you saw
4 in Augustine's brochure he really focused on this idea of
5 millions of germ-size particles coming out of the Bair
6 Hugger, but we know that it's only the particles that are in
7 the 2.5 micron and greater range that matter, and according
8 to the plaintiffs, they've to be ten microns or greater.

9 Well, let's look at the studies.

10 Albrecht's first study in 2009, he said that the
11 FAW blowers were emitting significant levels of internally
12 general airborne contamination in the .5 to 5 micron size
13 range. Well, as the Court has just seen, that is a pretty
14 broad distribution. We know that the particle counter
15 measures particles in several bands smaller than that and
16 that that's where most of the particles are, in that .3, .5
17 submicron level. Here, they're all lumped together up to
18 five microns, so we don't knee really know what he measured
19 at each level, and very likely he included in his count a
20 number, a large number, of particles that are too small to
21 be bacteria or to carry bacteria.

22 The next one in 2011, all he says about the
23 particle count is we counted particles greater than .3
24 micron. Well, that includes a whole lot of particles that
25 are too small to carry bacteria or to be bacteria. He

1 didn't break down which particle sizes he actually measured.

2 Reed in 2013, this is the final European crud and
3 bug study, again, greater than .3 micron pure cubic foot.
4 That's going to include a whole lot of particles that are
5 simply irrelevant.

6 Legg actually broke out the particles, particle
7 sizes that they counted in 2012, and you can see there's a
8 large number of .3 micron particles. I just obscured part
9 of that. Relatively small number of .5 micron particles,
10 and only 3.6 in the five micron size range. So out of all
11 of those particles, the only ones that are really relevant
12 are the ones in the 3.6 at the end there, the only ones that
13 are potentially relevant.

14 So, and then finally, the next Legg study from
15 2013 reported an alarming number of particles in the
16 forced-air warming group, 2,174,000 compared to only 1,000
17 for the radiant warming HotDog group. That's a very large
18 number of particles. What would account for that? Well, in
19 the method section of the paper, they disclose that they
20 wanted to visualize the air flow while they were doing this
21 experiment and so they rented this machine, a Rocket PS23
22 smoke machine, from Pea Soup Limited in Ingleby Barwick,
23 United Kingdom, and that machine was actually pumping out a
24 continuous flow of .3 micron glycerol tracer particles. So
25 the 2,174,000 particles, those are all being pumped out of

1 this machine and they're all .3 micron size particles which
2 everybody agrees are irrelevant because they're too small to
3 be bacteria or to carry bacteria.

4 All right. So that's what the studies show about
5 particles, but what about the ability to use particles to
6 actually predict bacteria in the air and the risk of
7 infection. And --

8 THE COURT: So hold that until after lunch?

9 MR. GOSS: Sure. Yes, ma'am.

10 THE COURT: We will be in recess until one clock.

11 THE CLERK: All rise.

12 (Court adjourned at 12:16 p.m.)

13
14 (1:08 p.m.)

15 THE COURT: Please be seated. All right.

16 Mr. Goss.

17 MR. GOSS: Thank you, Your Honors, if I may
18 continue. All right. So when we left off, we had just
19 finished talking about the particle counts that were shown
20 in these various studies and how actually a lot of important
21 information about the sizes of the particles had been left
22 out. Moving on from that, we turn to the question of what
23 can you do with that particle data as far as predicting
24 either bacteria in the air or bacteria in the wound or even
25 to go so far as to predict based on a particle count whether

1 somebody has a risk of infection? And what the case law
2 says is that for any of this to be admissible and for any of
3 this to carry plaintiffs' burden, you have to show that it's
4 able to reliably predict an effect in humans, and that's
5 what the *Prempro* case says, that you can use lab results but
6 you have to be able to explain how those lab results will
7 reliably predict effects in living humans, and the evidence
8 in this case is that you can't reliably predict based on
9 particle counts either bacteria in the air, bacteria in the
10 wound, or, further most from it, is actual risk of
11 infection.

12 This is a review that was published in 2016 before
13 the Darouiche study. It's a review by Mora of
14 microorganisms in confined habitats, microbial monitoring
15 and control of intensive care units, operating rooms, clean
16 rooms, and the international space station, because if
17 you're going to spend a bunch of time up there, you might be
18 concerned about bacteria in confined spaces, so this very
19 article reviewed all of the literature.

20 And with respect to using particle counts to
21 predict bacterial count in air, the reviewers noted that
22 many studies have argued that the results of the particle
23 count method do not correlate with the bacterial count
24 results. And they point out as examples the Landren paper
25 which is in the exhibits, Scaltriti which is unfortunately

1 not, and the Kristina study which is also in the exhibits.

2 They go on to say that only two studies have shown
3 that there is a correlation between the number of airborne
4 particles and the number of CFUs, and those are Celon and
5 Clark from 1990. And then 20 years later Stocks did it.
6 This is the Stocks paper from 2010, so it's a few years
7 before the international consensus meeting. This was
8 published and available in the worldwide literature.

9 And the interesting thing about both the Stocks
10 and the Darouiche papers is they actually have a common
11 theme and a common motivation. You'll notice that a
12 coauthor on the Stocks paper is this --

13 MR. GOSS: The author on the Stocks paper is this
14 gentleman named Sean Self, and he is the president and CEO
15 of a company called Nimbic Systems, and Nimbic Systems makes
16 a device for use in the operating room called the Air
17 Barrier System, and what it is, it's over here on the left
18 or on the right. Sorry.

19 It is a device that sucks air up from below the
20 operating table, by the looks of it, filters it, runs it
21 through a hose, and then this nozzle here is mounted to the
22 patient, and it blows air across the surgical wound. That
23 is the Air Barrier System that the Nimbic Systems Company
24 makes.

25 And this is Dr. Stocks here in a YouTube video

1 promoting the Air Barrier System, and naturally, if you're
2 selling a device that filters air in the operating room and
3 blows it over the surgical wound, you would want to try to
4 establish in the marketplace that it actually does
5 something, that it doesn't just reduce particles, but it
6 actually reduces bacteria and reduces the risk of infection,
7 and so that was the motivation for both the Stocks study and
8 the Darouiche study.

9 Here's a picture of the Air Barrier System from
10 the -- this is actually from the Darouiche article. Counsel
11 mentioned that this was a randomized double-blind controlled
12 trial, and it was to prove the effectiveness of this Air
13 Barrier System. So you can see what they do with it. They
14 take this nozzle, and they mount it to the patient's torso,
15 and then it blows right over the surgical wound, and this is
16 a diagram of their test setup in Darouiche where they the
17 nozzle blowing air right over the wound, and then they have
18 these tubes to collect airborne CFUs and particle sampling.

19 And so it's a bit ironic, but the plaintiffs are
20 relying for their proof of correlation to particles and to
21 bacteria on tests designed to validate a device that blows
22 air in the operating room. Nevertheless, going to the
23 Stocks article, the authors noted that they only found
24 correlation for particles of 10 microns in size or greater.

25 And they said even for that group of particles,

1 the correlation or the precision of predicting the counts
2 was limited, and if you look at their data, you can see why.
3 So here on this axis you have the colony forming units, and
4 here you have the numbers of 10 micron particles per cubic
5 meter.

6 For all of the dots, that's their data, and you
7 can see it's kind of all over the place, and these lines are
8 their confidence intervals. And what our microbiologist
9 Dr. Jim Ho will tell you, he's an expert in airborne
10 bacteria, is that this distance is the size of a mile, and
11 that means you can't make reliable predictions based on that
12 data in terms of determining from a particle count how many
13 10 micron bacteria you're going to have per cubic meter.

14 So I'll come back here, and now Darouiche. The
15 problem with Darouiche is, the authors noted in their
16 methods that they took particle counts at each of these
17 sizes .3 microns, .5 microns, 1 microns, 5 microns and
18 greater than 10 microns, but they didn't report the
19 breakdown by size. Instead, if you look at the results in
20 Table 2, this is for total hip arthroplasty, they list it as
21 total particulate.

22 So just like Legg and Albrecht, they lumped all
23 the particles together. So that's how you get these larger
24 numbers of particles and then these small numbers of CFUs,
25 but we know within that roughly 200,000 particles, there are

1 a whole lot of particles that are too small to be bacteria
2 or to carry bacteria. So how can you make a reliable
3 correlation, knowing that those large numbers are simply not
4 going to be bacteria or even capable of carrying bacteria?

5 After the Darouiche study came out, this is from
6 the Nimbic Systems Facebook page. They posted it. They say
7 the Air Barrier System was featured in a ground-breaking
8 clinical trial demonstrating a reduction in costly implant
9 infections, and you'll notice the title is the same, it is
10 Darouiche. The Association of Airborne Micro Organisms in
11 the Operating Room with Implant Infections.

12 And then down here we've got Sean Self saying,
13 this is great research. All right. And the point of this
14 is not to say that it is a terrible study, that it's, you
15 know, this bias ruins it completely, but it was done for a
16 reason. And that reason is, once again, marketing based,
17 and it raises a question for the Court beyond the fact that
18 the data doesn't support a correlation, it's another indicia
19 of unreliability the Court should take into account in
20 deciding whether the plaintiffs can meet their burden in
21 this case.

22 We also heard a lot about how Darouiche correlated
23 the number of bacteria with the risk of infection. So
24 setting aside the lack of correlation between particles and
25 bacteria, Darouiche reported a correlation between bacteria

1 levels and infection. The problem is, Darouiche didn't
2 actually try to determine whether the species detected in
3 the air was the same as the species that the plaintiffs
4 later developed in their infections.

5 And that's important because in this study by
6 Birgand in 2015, the authors actually found that the air
7 contamination was not significantly associated with the
8 wound contamination. So they actually cultured what was in
9 the air, and they found that what was in the air were
10 species than what they swabbed out of the surgical wounds,
11 which they did in that case.

12 And so they say, A large number of surgical wounds
13 are contaminated at closure. Organisms may be endogenous
14 and arise from patient skin flora, or they may be exogenous
15 arising from the surgical team or in the air. This
16 combination of endogenous and exogenous organisms can
17 confound the relationship between the quantitative presence
18 of organisms in the air and those colonizing the wound
19 during the surgery.

20 In other words, just because you have bacteria in
21 the air, you can't assume that a subsequent infection came
22 from the air and that the bugs that gave rise to the
23 infection are the same as the ones that were in the air
24 during the surgery. There has to be a correlation, and that
25 wasn't shown in Darouiche.

1 And I also want to come back to the Albrecht work
2 because unlike Darouiche and Stocks, which are we looking at
3 the Air Barrier System, Albrecht was actually testing the
4 Bair Hugger system, and he was trying to correlate particle
5 counts in these different size ranges with bacteria. And
6 he, of course, found no correlation, and that's the most
7 relevant data we have on any attempt to correlate with the
8 Bair Hugger.

9 I want to turn now to one of plaintiffs experts,
10 Mr. Koenigshofer, who is the only expert of the plaintiffs
11 who really touches on this issue of the filter. He will
12 tell you that he's not a filter efficiency expert. He's not
13 an expert in the method used to determine filter efficiency,
14 but he does say that the Bair Hugger filters are less
15 efficient than what's in hospital HVAC systems, and that's
16 not quite right.

17 The Bair Hugger filters actually do meet a
18 standard that's set by the American Society of Heating,
19 Refrigeration & Air Conditioning Engineers. That's the
20 industry body that sets regulations for or industry
21 standards, I should say, for filter efficiency. And
22 Mr. Koenigshofer is a member of it.

23 Our expert Michael Keene is a member of ASHRAE,
24 and the standard that applies to filtration in operating
25 rooms is 170, and that's right here, ASHRAE 170. What

1 ASHRAE 170 says is, in operating rooms for Class B and C
2 surgery, which would include ortho, the minimum requirement
3 for filtration, they have two filter banks. One is kind of
4 a pre filter, and then the filter bank number two is the
5 final filter that filters the air going over the patient,
6 you have need a rating of MERV14.

7 And in fact the filters used in the Bair Hugger
8 devices are MERV14 and have never been lower than MERV14, at
9 least for the model 505 and 750, the models that will be at
10 issue in these cases, and the ASHRAE 52.2 standard is the
11 standard for determining filter efficiency. That's how you
12 get to a MERV rating, and they have a very specific test
13 method, and you determine the efficiency based on how well
14 the filter captures particles in three size ranges .3 to 1,
15 1 to 3 and 3 to 10.

16 So for MERV14, you have to filter at least
17 75 percent of particles between .3 and 1, more than
18 90 percent of particles between 1 and 3, and more than
19 90 percent of particles between 3 and 10. And just to give
20 the Court some perspective on the size of the particles
21 we're dealing with, typical human hair is 75 microns thick,
22 and the particles that we're filtering with an MERV14 filter
23 are down in this size range at the bottom here, .3 --
24 sorry -- .31, 3.0 and 10.0.

25 And the typical shed skin cell is between 10 and

1 50 microns. So again to give you some perspective, if you
2 can filter pretty well at this level, then you're not going
3 to have much trouble filtering things that are that big.

4 All right. This is a filter efficiency test
5 result that 3M obtained from a lab in Bloomington, LMS Labs,
6 for a Bair Hugger filter, and it's done according to test
7 standard 52.2, 2012, and by the way, this is a specification
8 that 3M has imposed on its filter supplier. They have to
9 occasionally pull filters and submit them for testing to
10 make sure that they meet this MERV14 standard.

11 And the results show for the .3 to 1 micron range,
12 it captures 81.5; for 1 to 3, 98.7; 3 to 10 microns, 100
13 percent. So just to compare it to the standard, here's just
14 a comparison of the standard against these test results.
15 For those smallest particles, you've got to be above
16 75 percent. We exceed that. For the next range, you got to
17 be better than 90 percent. We have exceed that, and for the
18 final range, we are at 100 percent.

19 And by the way, it's important for me to provide
20 some context, too. There's no FDA regulation that requires
21 warming devices to have a filter of any sort. There's no
22 FDA regulation that applies to any fan blowing devices in
23 the operating room that will require any level of filtration
24 so this is a voluntary --

25 THE COURT: It's filtering the air that is taken

1 up from the unit and then goes into the hose, or is it at
2 the end of the hose, or where is this?

3 MR. GOSS: Yes. Great question, Your Honor. It's
4 right at the intake of the device, and so the plaintiffs
5 have said the device sits on the floor. I mean, it can sit
6 on the floor, but it actually has a hook mount. I don't
7 know if you remember from science day. We had one of
8 these --

9 THE COURT: But wherever it sits, the filter, the
10 filter is only relevant to what goes into the Bair Hugger,
11 not goes out and also not relevant -- so not to any
12 expulsion of bacteria that might be already in the unit
13 itself or -- and it also doesn't have anything to say about
14 the air disruption.

15 To the extent you've got air coming, you know, the
16 air disruption wouldn't be affected by a filter, and
17 anything coming out of the unit itself wouldn't be affected
18 by the filter, but this would affect the mechanism of
19 drawing micro organisms from the floor into the Bair Hugger
20 and then onto the patient or into the air, right?

21 MR. GOSS: That's right, Your Honor. It's
22 designed to filter out the intake, and again, that's whether
23 it's on the floor or -- and it's often mounted to the pole.
24 We also sell rolling carts so you can put it on the cart.
25 It is more ergonomic for the CRNA.

1 THE COURT: Wherever it is.

2 MR. GOSS: Wherever it is, but you're right, Your
3 Honor. The filter it about the intake, and it doesn't have
4 any impact on the air flow, other than to slow the air flow
5 somewhat because it's got to go through the filter, but it's
6 a completely separate issue from the plaintiffs' air flow
7 disruption theory.

8 All right. So you can see with this result, you
9 know, we're filtering 100 percent of the particles between 3
10 and 10 microns, and the standard only calls for 90 percent,
11 and we know that skin cells are at least that big and often
12 bigger. Then it really comes as no surprise that the ASHRAE
13 filter efficiency standard when they look at what kinds of
14 contaminants should be controlled by which filters, they say
15 that filters in this range of MERV13 to 16 are appropriate
16 for controlling all bacteria because we know that bacteria
17 is either going to be in a cluster, or it's going to ride on
18 a particle that is of a size that is going to be easily
19 filtered by filters in that class.

20 So HEPA, just so the Court understands, HEPA is
21 focused on filtering particles that are below 1 micron.
22 Those are the tiny particles that aren't relevant to the
23 question of airborne bacteria. So for this application,
24 ASHRAE, the authority for establishing filtration efficiency
25 standards, they say that this is appropriate for all

1 bacteria, and that's what the Bair Hugger filter is. It's
2 an MERV14.

3 I want to turn to Dr. Elghobashi and the CFD
4 simulation that he, actually he was retained by the
5 plaintiffs, but he had a colleague of his, Dr. Apte actually
6 run the software to come up with the model, but he started
7 out by visiting an operating room. This is a picture from
8 his report. I believe it was in Santa Monica, and they had
9 someone prepped and draped for a knee surgery.

10 And you can sort of see from the lines that they
11 took a bunch of measurements so that they could get the
12 measurements right in the CAD drawing that they were going
13 to use for the model. So they got out the ruler and
14 measured the size of the drapes, and they came up with this
15 schematic and identified a few key features.

16 So they have the knee area here, the Bair Hugger
17 here, and actually it looks like it's sitting on a cart
18 there. I'm not sure if that's what was intended or not, but
19 then the critical boundary condition in the model is this
20 area around the surgical drape, which is meant to mimic
21 this.

22 And what Dr. Elghobashi assumed for his model is
23 that all the air leaving the Bair Hugger blanket is going to
24 come out the edges of this drape, and it's going to come out
25 at the same temperature and at the same velocity all around

1 that edge. So and again, this same applies over here, that
2 the air is all coming out. For the most part it's coming
3 out this way.

4 Now, in truth, where the air really comes out is
5 around the head and neck of the patient, and there are
6 several studies that comment on that. That's where most of
7 the air comes out is around the head and neck, but this is
8 where Dr. Elghobashi assumed that the air was coming out,
9 and he assumed certain conditions relating to that.

10 So I apologize that this is a bit small, but he
11 says a Dirichlet boundary condition is applied such that the
12 air injected into the room perpendicular to the edges of the
13 drape with this calculation, and what the calculation says
14 is, it's going to come out at a certain velocity,
15 .2694 meters per second, which translates to 53 feet per
16 minute, and then the temperature of the air leaving it is
17 going to be 106 degrees or 41 degrees Celsius.

18 So those are the key conditions, that the air
19 coming out here and here is going to be coming out at
20 106 degrees and 53 feet per minute all around that boundary,
21 and he didn't actually measure that. He assumed it, and he
22 was asked in his deposition, Well, why didn't you take
23 measurements to try to see what was actually coming out
24 around that drape boundary? And he was asked, You thought
25 it was unnecessary to obtain those instruments and to do the

1 preparation necessary to actually measure the temperature;
2 is that right?

3 Well, I never thought unnecessary.

4 Well, you never thought it was unnecessary?

5 Correct.

6 So you thought it was necessary?

7 Well, yes.

8 Well, why didn't you do it?

9 I substituted by thinking hard. That is what he
10 said.

11 Now I will readily concede that is he a brilliant
12 man, but no amount of thinking is a substitute for empirical
13 measurement when you're trying to make sure that you have
14 got valid inputs for a computer model, especially a very
15 expensive one like this. I think plaintiffs said they spent
16 about \$120,000 on it. You want to make sure you get it
17 right.

18 He said, Well, I didn't have the equipment with
19 me, and it's very expensive and laborious to get everything
20 together that you need to make sure that you get the
21 temperature right and the velocity right for measurements.

22 Well, there's a company here in St. Paul called
23 TSI that makes these devices called Hot Wire anemometers. A
24 lot of companies make these. You can buy them on Amazon.
25 This is kind of a nicer one, but it costs 1,00, 2,000 bucks,

1 something like that. You can get them more cheaply on
2 Amazon for less than \$200, and our mechanical engineering
3 filter expert from the University of Minnesota, Dr. Tom
4 Keene, said, well, something about this assumption of
5 106 degrees and 53 feet per minute doesn't sound right, so I
6 want to check it out. You know, do you guys, can you take
7 me somewhere where I can actually see what comes out of the
8 drape?

9 And this is just the readout that you get from the
10 an meter. The big number is the velocity in feet per
11 minute, and then there is temperature and relative humidity.
12 So we took Dr. Keene over to 3M campus, and we had a room,
13 not an operating room, but a room where we had a draped
14 mannequin set up. There were a couple of nurses,
15 consultants to 3M, that prepped and draped the mannequin in
16 the usual way.

17 And he used the anemometer. You can see this wand
18 here to measure the temperature at the edge of the drape
19 with the Bair Hugger off, and he got 67.3 degrees and 2 feet
20 per minute. Then he turned it on just on ambient air,
21 66 degrees and 3 feet per minute, and then he turned it on
22 with the warm air setting, and the highest he got after
23 waiting a few minutes was 72 degrees, 4 feet per minute.

24 Now plaintiffs are going to tell you that there
25 are all kinds of problems with Dr. Keene's temperature

1 readings, but literally all he was doing was taking this Hot
2 Wire anemometer and this wand and saying, okay, if I put
3 this next to the drape edge, what do I get? Do I get
4 anything close to what Dr. Elghobashi assumed?

5 THE COURT: Did Dr. Elghobashi come up with that
6 106 by looking at Bair Hugger marketing material that said
7 that the temperature that comes out is 106 or 105 earlier?

8 MR. GOSS: Yes, he did. He said he assumed that
9 temperature based on what the reported temperature was in
10 3M's CFD, which was actually shown at science day, and it's
11 been available on YouTube for quite some time.

12 THE COURT: So why is 3M saying it comes out at
13 106 if it comes out at 72?

14 MR. GOSS: Right. And the difference has a lot to
15 do with the burden of proof. So Dr. Abraham, who built our
16 model, was assuming a worst case scenario. We know that the
17 device is calibrated for 43 degrees Celsius at the end of
18 the end of the hose, 109 Fahrenheit. So he said, I'm going
19 to assume that it only goes down a little bit because I want
20 to test the worst case to see does this disrupt the air in
21 my model?

22 And so he assumed a very high model, a high
23 temperature in order to really give the plaintiffs' argument
24 the best chance it had to disrupt the air flow over the
25 operating room table in his model, and it actually didn't.

1 Now, a lot of it has to do, a lot of the difference has to
2 do with where the air is coming out, where the air is coming
3 out and how it's coming out.

4 So Dr. Abraham took the studies that there were
5 and said, well, most of the air is coming out of the head
6 and neck area, and he used a larger area. So you're not
7 going to have as high a velocity for one thing, but
8 Dr. Elghobashi says, it's all coming out here, but again,
9 the main difference is the fact that Dr. Abraham wanted to
10 model a worst case scenario.

11 The plaintiffs are trying to prove, based on this
12 CFD alone, that there is a positive association and a causal
13 relationship between the Bair Hugger and airborne bacteria.
14 It's very different. We're just using ours through
15 Dr. Abraham as a demonstrative to say, in this hospital,
16 which is modelled after a hospital OR at Fairview Southdale,
17 and only at that OR, the Bair Hugger didn't disrupt the air
18 flow.

19 So we're not really trying to generalize. It's a
20 demonstrative from that situation. Whereas, the plaintiffs
21 are saying based on this CFD alone, we think the
22 international consensus should change, we think this case
23 should go to a jury. So a very different use of CFD. Okay.

24 Others took measurements. So another one of our
25 experts who did the Schlieren images, Dr. Settles, he took

1 temperature measurements around a draped mannequin, and the
2 highest temperature he got was 75 degrees. Actually, in 75
3 in that setup, and then under the drape he got up to 82, but
4 still a far cry from 106 degrees.

5 One of the studies that the plaintiffs rely on,
6 the Legg study, they took temperature readings of the drape.
7 So bar chart showing the theater and drape temperatures for
8 the various types of warming, where the highest they got for
9 forced air warming was 27 degrees Celsius, 80 degrees
10 Fahrenheit.

11 So what you see is, they're just isn't anyone
12 measuring a temperature even close to what Dr. Elghobashi
13 assumed. Dr. David, another one of plaintiffs' experts, he
14 actually tested a Bair Hugger blanket right under the
15 blanket to see what temperature he could get, and he only
16 got 36 degrees. Now he says, well, it was a used Bair
17 Hugger unit that I bought off eBay and had fault codes, and
18 I don't know. Maybe something was wrong with it.

19 But the highest temperature he got was 36 degrees
20 Celsius, which is still significantly less than the
21 41 degrees Celsius that Elghobashi assumed. Nevertheless,
22 based on this model, we have these huge clouds developing,
23 storm clouds over the operating table. Well, if you assume
24 the higher degree of energy in temperature and velocity for
25 your model, you're going to put a lot more energy into that

1 model, and you're going to see this kind of result.

2 And this is how you might say that a hurricane
3 could make landfall in Missouri or Minnesota, by putting
4 that much more energy into the system, into the model,
5 you're going to get a skewed result, and what plaintiffs
6 really want to show is that their computer model, and it was
7 done with a computer of which there is only ten in the
8 world, one out of ten in the world, that super computer and
9 their indisputably highly qualified expert, managed to put
10 the bacterial bugs in the knee, and that's their proof of
11 causation.

12 Well, it's only as good as the inputs, and there
13 just isn't reliable support for the inputs, and
14 Dr. Elghobashi did not do any sort of experiment in the real
15 world to see, is the result of this model valid? He didn't
16 do it. Now Dr. Abraham testified -- well, he didn't
17 testify. He was at science day and talked about the
18 importance of validation and how he got burned once when he
19 did a model without validating it and it was proven to be
20 incorrect.

21 After that, he learned to validate, and so what he
22 did with his CFD is, he then went to the same hospital at
23 Fairview Southdale, the same operating room, and did an
24 experiment with a fogger to see, well, does the fog water
25 vapor get over the operating room table with the Bair Hugger

1 on? And the experiment showed, no, it didn't. So it was
2 consistent with the results of his model.

3 Dr. Elghobashi did not do any sort of flow
4 visualization experiment to show anything resembling the
5 storm clouds amassing over the operating table that you see
6 in his model. The other thing that --

7 THE COURT: Why don't most of the air come out by
8 the head and shoulders? Is it not taped there or something?

9 MR. GOSS: Yeah, that is basically where it's not
10 taped there so that it's kind of directed away from the
11 anesthesia screen. I think I would refer to my partner, the
12 former OR nurse, to answer that question if I could, but my
13 understanding is that it's not taped, and it's kind of all
14 directed in that area. It's not to say that air doesn't get
15 out in other places, but most of it is going out the head
16 and neck, and I think it's even the McGovern study that says
17 that.

18 The other thing that Dr. Elghobashi does not take
19 on directly in his report is work done by the National
20 Institutes of Health. There's a CFD expert there named
21 Farhad Memarzadeh who actually has done a lot of work with
22 CFD in operating rooms, and the ASHRAE 170 standards are
23 largely based on work that he has done, and he modelled a
24 Bair Hugger into his operating room model to see is this
25 going to have an effect on air flow.

1 And what he concluded and he says, speaking for
2 the NIH, NIH concluded that in both scenarios there is
3 0 percent deposition on the patient for the contaminant
4 sources and the heat generated by the patient provides some
5 protection, and that last bit is important because the
6 patient actually generates some heat, and my partner who
7 will talk about Sclieren, shows there is a thermal plume
8 that can actually be protective.

9 So when things are falling with these tiny
10 particles, your own heat wave can kind of push them to the
11 side, and the idea behind the velocity in the OR is, you
12 don't want it to be so fast that it actually disrupts your
13 own protective thermal plume, and so that's what he's saying
14 her, that the Bair Hugger doesn't disrupt, doesn't cause
15 particles to fall into the surgical site, and the heat
16 generated by the patient provides some protection.

17 And he says, This investigation validates
18 Moretti's conclusion that forced air warming technology does
19 not increase the risk of surgical wound infection. Now,
20 what Dr. Elghobashi says in his report, he looked at earlier
21 work by Dr. Memarzadeh or Memarzadeh -- I never know quite
22 which -- did not include the Bair Hugger.

23 And he says, well, that work used a different set
24 of equations. He used the Reynolds average Navier Stokes
25 equations, and for reasons that I wouldn't be able to

1 understand, that isn't a valid model. They should have used
2 large-eddy simulations, but what Dr. Memarzadeh does not
3 take on directly is this specific work by Memarzadeh looking
4 at the Bair Hugger and saying, my model shows Moretti was
5 right. It doesn't increase the risk of surgical wound
6 infection.

7 Just quickly want to turn to Dr. David because he
8 doesn't have a lot to say about general causation. He did a
9 literature review and included all of the Augustine studies
10 and essentially none of the negative bacteria studies, or at
11 least he doesn't comment on any of those. And I would just
12 point the Courts to this decision in the Rezulin MDL where
13 the Court held, If the relevant scientific literature
14 contains evidence tending to refute the expert's theory and
15 the expert does not acknowledge or account for that
16 evidence, the expert's opinion is unreliable.

17 And that's what we're saying is true of Dr. David.
18 He looked at all of the Augustine exploratory studies, but
19 he really didn't address in his report or his opinions the
20 nine published studies finding no bacteria. So I want to
21 come back to what Augustine himself said about -- actually,
22 this was in reference to Reed saying, why don't we try to
23 swab surgical wounds and see if we can match bacteria to
24 bacteria in the air when we're using the Bair Hugger.

25 And Augustine says, well, I don't think it's

1 really such a good idea. It would simply be another
2 intermediate step similar to particle detection over the
3 wound. In other words, it does not conclusively answer the
4 question of, does forced air warming cause wound infections,
5 and that's where we are at the end of all of this, is
6 attempts to look at intermediate steps that don't actually
7 correlate.

8 There are tremendous analytical gaps between all
9 of these steps, and they do not conclusively answer the
10 question, Does forced air warming cause wound infection?
11 And I'll just finish with a quote. This is ripped from the
12 headlines. My partner Ben Hulse sent this to me this
13 morning. This is from the Second Circuit who yesterday
14 upheld the exclusion of the plaintiffs' experts in the
15 Mirena MDL.

16 And what the Second Circuit said in looking at the
17 trial court's exclusion of the plaintiffs experts, they
18 said, Finding no direct support in the literature for
19 secondary perforation -- which was the issue in this case.
20 It's about a birth control device, and the question was
21 whether it could cause injury to the uterine lining --
22 having conducted no prior research on the subject, the
23 experts all assumed the existence of the very phenomenon in
24 dispute and then hypothesize how it could occur. The
25 experts thus begged the very question they were trying to

1 answer, and that's exactly what's going on here, Your Honor.

2 Unless the Court has any other questions, I'm
3 finished.

4 THE COURT: Thank you.

5 JUDGE LEARY: Thank you.

6 MR. GOSS: Thanks.

7 THE COURT: Where did Ben Gordon go?

8 MS. ZIMMERMAN: If I may, Your Honor, he's had a
9 severe migraine. He's actually sends his regrets.

10 THE COURT: Tell him I hope he feels better.

11 MS. ZIMMERMAN: I will.

12 THE COURT: But don't tell him it took half a day
13 to notice him. I suppose it would be a felony to offer him
14 medication. Does he have what he needs?

15 MS. ZIMMERMAN: He has Imitrex but without much
16 success.

17 THE COURT: Mr. Assaad.

18 MR. ASSAAD: Thank you, Your Honor. I'm just
19 trying to figure out where to begin.

20 I've been sitting here, and I've been hearing a
21 lot of studies go up, especially about the Moretti study,
22 about what it actually means, and the defense has stood up
23 here talking about Augustine and about studies and what they
24 mean. Very little was discussed regarding the methodology
25 that Dr. Elghobashi used.

1 They've been focusing on the weight of the
2 evidence, instead of what this Court is here to decide:
3 Whether or not the experts used proper methodology, whether
4 or not they applied the correct methodology that is used and
5 generally accepted, and whether or not Moretti says the
6 bacteria increases over this part or over that part or what
7 Oguz says, that's for the jury to decide, not for this Court
8 to decide.

9 And I stand up here trying to figure out what do I
10 need to address, because it's very difficult when you hear
11 all these opinions of, as the Court likes to call it, lawyer
12 talk about what stuff means and not actually putting
13 evidence of what the methodology is or what the experts are.

14 And ironically they cited Memarzadeh regarding his
15 CFD studies to show what the ASHRAE standards are based on,
16 and what's ironic or what's actually true is Memarzadeh, who
17 they consider an expert from the NIH, the ASHRAE standards
18 of the air flow in an operating room, the uni directional
19 air flow that is the minimum standards, and that's why we
20 believe that most operating rooms have uni directional air
21 flow because of ASHRAE, and many states have adopted ASHRAE
22 as the minimum standards for operating room, and that's why
23 most operating rooms have uni directional air flow.

24 All the studies Memarzadeh did he did on a CFD
25 because the CFD is a test. You cannot measure particles

1 simply by using a \$30 anemometer or velocity. As it's
2 stated numerous times in our expert report, you need a
3 particle intensity velocimeter, PIV, that you have to stick
4 in an operating room for over two months and take particle
5 measurements to figure out the turbulent intensity that CFD
6 would do.

7 And that is why computational fluid dynamics is a
8 test. You don't have to do another test. If that was the
9 case, companies would be spelling billion and billions of
10 dollars to do a test on a CFD study that they have done.
11 Right now the United States does all their nuclear bomb
12 testing on CFD. CFD is used in medicine, and I'll talk
13 about that with what Elghobashi has done, how CFD without
14 doing a test is able to have surgeons go in and solve an
15 upper airway respiratory defect in children.

16 THE COURT: So it matters, of course, what the
17 inputs are with CFD. I don't think anyone disputes that CFD
18 is really valuable. What say you with respect to the 106
19 temperature assumption?

20 MR. ASSAAD: I'll go to that, but just assuming
21 that the inputs are disagreed upon, that's for the trier of
22 fact, and the case law is very clear. That does not go to
23 methodology. That's what we fight about in the courtroom.

24 THE COURT: Just tell me where your expert came up
25 with the 106, why that is consistent with good scientific

1 practice when you're going to run the CFD? Why -- and
2 temperature is an important component. Why do you not --
3 outside the litigation context, would you not test to see
4 what the right temperature input would be?

5 MR. ASSAAD: Because it's in their operating
6 manual of what the output temperature -- it's on the Bair
7 Hugger.

8 THE COURT: Does say it's coming out all over?

9 MR. ASSAAD: It is at 43 degrees. Okay. Then 3M
10 has provided a, we have testing dots of 3M which I'll show
11 you that says the temperature that comes out at the blanket,
12 because there is a loss in temperature from the entrance to
13 the blanket, comes occupant at 41 to 42 degrees. Now you
14 have to consider what is going on here.

15 The CFD that Dr. Elghobashi did and the studies
16 and the calculations which I'll show you that he did by
17 hand, they only showed you part of the transcript. They
18 didn't show you the entire transcript. You have a surgical
19 drape over the body, over the drape. Then you have another
20 drape over the Bair Hugger, and you saw that picture. It's
21 very, I would say, drape intensive.

22 It's creating an insulated area. Just, for
23 example, you go to a room, and you put in a space heater in
24 this room. It's going to take a while to heat up the room
25 on a single space heater, but you go to your small office.

1 It's going to be much quicker. The area under the operating
2 room table where all the drapes are is an insulated area,
3 and what he calculated, and you will see through the
4 calculations that is he did, it wasn't an instantaneous
5 time, you know, like you turn the Bair Hugger, and
6 underneath the operating room table and underneath the
7 drapes is 40 degrees.

8 In fact, it takes about six minutes for the Bair
9 Hugger to even warm up to even 43 degrees to come out of the
10 hose, but he did his calculations based on --

11 THE COURT: And he never measured the temperature
12 at all. He doesn't know how long it takes to get to 43
13 because he never measured to 43 ever.

14 MR. ASSAAD: Well, that's internal 3M documents.

15 THE COURT: No. Elghobashi doesn't say he
16 measured it.

17 MR. ASSAAD: No. He's relying on 3M documents.
18 Yes.

19 THE COURT: I know, but he can't say it takes six
20 minutes to get up to this temperature because he never took
21 the temperature.

22 MR. ASSAAD: We can rely on 3M's documents.

23 THE COURT: They say they're marketing documents,
24 so was it consistent with his non-litigation practice to
25 rely on marketing documents, I think that's what they said.

1 MR. ASSAAD: Also as it's consistent with his
2 non-litigation practice to rely on 3M's testing documents,
3 just like Memarzadeh did in his study where he put the exit
4 temperature at 106 degrees as well. So it's Memarzadeh who
5 is there CFD expert and it's generally accepted. But
6 regardless, Your Honor, that goes to the weight of the
7 testimony. They could argue all they want, and they'll have
8 Abraham and potentially only some of Dr. Kuhn and Settles to
9 come in to measure the temperature.

10 But the funny thing is, they showed Settles that
11 showed the temperature was 85 degrees underneath the
12 operating room table. You saw that picture. That was done
13 only after a minute or two. They didn't leave the Bair
14 Hugger for 30 minutes. Dr. Elghobashi used calculations,
15 which I'll show you, that he calculated the air underneath
16 the operating room table. And that's based on general
17 accepted principles of science that have been out for
18 hundreds of years. We're talking about, like, the heat
19 transfer equations, fluid dynamics equations, the
20 Navier-Stokes equations. Those are all general accepted
21 principles that I don't think anyone is going to come in
22 here and say that that methodology is incorrect.

23 What Dr. Elghobashi did is a real life model.
24 They don't agree with it and they're going to argue against
25 the boundary conditions, but the case law is very clear, and

1 that's -- we've cited cases, and I'll cite to them. Even if
2 you use the wrong equation for the wrong boundary equation,
3 as long as you use the correct methodology, it's admissible.
4 All that goes to the weight.

5 Let's talk about the qualifications of
6 Dr. Elghobashi. He has received the DSC, the higher
7 doctorate award, from the Imperial College of London. That
8 is higher than a Ph.D. It is where they looked --
9 throughout your years, they look at your contribution to
10 science. And his contribution is on particle flow, particle
11 transfer and turbulent flow, exactly what he is solving
12 here.

13 He's also the National Academy for Engineering for
14 contributions to understanding and modeling of multiphase
15 turbulent flows. And actually, there's even a particle map
16 called the Elghobashi map that's been cited so many times in
17 the literature that discusses the particle-to-particle
18 interactions in turbulent flow. His credentials are
19 impeccable, probably one of the top two or three people in
20 the United States, if not the world.

21 Defendants' experts agree that he's an expert and
22 that he did the equations and calculations correctly.
23 That's Dr. Kuehn, a professor at the University of
24 Minnesota, not a neuro engineer telling this Court that
25 Elghobashi did it incorrectly. This is an engineering

1 professor. And by the way, off topic, Your Honor, I'm also
2 an engineer so I can kind of understand this stuff a little
3 bit.

4 THE COURT: You know, I wish I could say I was an
5 engineer. I was raised by engineers and statisticians, so I
6 can smell it a mile away.

7 MR. ASSAAD: Even Dr. Settles states that he's an
8 expert in computational fluid dynamics. He even says it's a
9 very elaborate CFD solution of simulated OR with staff,
10 overhead lights, side tables, and a patient fitted with a
11 forced-air warming blanket. That's more than what Abraham
12 did. Abraham didn't have people, didn't have -- didn't put
13 any types of temperature grading from the lights. He did a
14 real life world test.

15 Now, really the argument stops here because the
16 defense admits that CFD is reliable method, and, in fact,
17 and in fact, if I heard correctly, they even admitted that
18 the kinetic energy in an operating room, they're going to
19 argue about it, actually causes particles to rise. That's
20 what Peter Go ss said.

21 The defendants claim three issues, that Elghobashi
22 relied on Augustine's opinions. That is not correct. There
23 is nothing in his report that he relied upon in anything
24 that Augustine has stated. They also argue that
25 Elghobashi's boundary positions are incorrect. That's for

1 the jury to decide. That doesn't go to methodology. They
2 also argue that Elghobashi did not test his results. Again,
3 they have not shown that the methodology that people in
4 Elghobashi's area of expertise use require testing the
5 results. That's what CFD is for. CFD is the test.
6 Memarzadeh did not test his results to determine that -- and
7 which many hospitals rely upon that you should have 20 air
8 exchanges per hour in an operating room and what is the
9 speed of the diffuser, the velocity, coming down in inter
10 directional flow? Memarzadeh doesn't test his results with
11 going in there with a PIV and measuring particles because
12 it's millions and millions of dollars to do that type of
13 test. We'd have to -- we'd have to rent a --

14 THE COURT: Would you just hold on? I'm so busy
15 getting ready to ask you my question that I'm not listening
16 to, so let me just spit this out and then I'll be listening
17 to you. And the last thing I heard you say was millions and
18 millions of dollars.

19 Does Dr. Elghobashi's report permit a modified
20 opinion for if they change the input or this is the millions
21 and millions of dollars? Could he change from instead of
22 106, could he plug in 80 or 87 or some of the actual, you
23 know, like some number that came from an actual measurement?
24 Would his value to the jury extend to saying, okay, well,
25 this is the model if it's 106, but if it's 80, then it's

1 this? Or is that outside his -- he did the one model with
2 this --

3 MR. ASSAAD: Well, the model can be changed. The
4 model's a CFD model and you could change the input. It
5 takes a while because, as you see from the report, if you
6 see from the report, it took two million CFU hours to model,
7 1600 cores at the University of Texas Stampede supercomputer
8 that he used 1600 cores to run the model. I mean, this is
9 high calculations.

10 THE COURT: Right. But does his opinion contain
11 any way of assessing how, you know, if it's not 106, if it's
12 105 what does one degree do to this? What does -- is there
13 any basis for a determination of the helpfulness of that
14 model in a world where the 106 not assumed?

15 MR. ASSAAD: Well, the 106 degrees, Your Honor, is
16 a number of 3M.

17 THE COURT: No, I know that.

18 MR. ASSAAD: Okay.

19 THE COURT: I know that. But --

20 MR. ASSAAD: So I guess I'm trying to understand
21 if it's 3M --

22 THE COURT: I'm just thinking about the usefulness
23 of the model, and if the defendants are saying part of the
24 evaluating methodology is have you -- is proper methodology
25 inclusive of proper inputs. If the Court is persuaded that,

1 from a scientific standpoint, the firm assumption of 106
2 isn't sufficiently grounded and it flies in the face of
3 every actual test that shows that it's not 106, he could
4 still be useful if what he shows is if some different
5 temperature you also have -- this effect remains if the
6 temperature is in some range or does is his opinion
7 inextricably bound to an actual output temperature of 106?

8 MR. ASSAAD: No, it's not, Your Honor.

9 THE COURT: Okay.

10 MR. ASSAAD: And I'll explain why, because that's
11 just a model he used. If it was 105 or 104, it would just
12 take longer. It's about kinetic energy.

13 THE COURT: And is that what -- is that in his
14 report somewhere that he says if it's, say -- and I bet he
15 doesn't say 80, but if it's 80 it's going to take longer or
16 what --

17 MR. ASSAAD: It would denied on the case specific
18 case because it will depend on what the temperature was set,
19 which is most likely 43 degrees, but I do not -- I believe
20 there's room in his report that it is a model and it's up to
21 -- I mean it's -- the model is the base of his opinions, but
22 it's just to show what exactly happens.

23 I want to show you this document because this is a
24 3M document, Your Honor, that talks about the testing that
25 3M has done internally about the temperature where the 750

1 warming unit and a 522 blanket which Dr. Elghobashi relies
2 upon in his document and his report. If you look at the
3 code, it says under there MCST, which is the average
4 temperature across the blanket. And if you look over here,
5 there are testings between two different blankets, a new
6 522, which is an upper body blanket, and they have a
7 standard 522.

8 THE COURT: So are they -- that's the temperature
9 of the actual blanket?

10 MR. ASSAAD: That's the temperature of the ai --
11 what they did, Your Honor, and --

12 THE COURT: Because it says temperature of
13 blanket.

14 MR. ASSAAD: Yes, that is the temperature of the
15 air coming out of the blanket. That's 3M's testing. That's
16 what we're relying upon. This is their measurements outside
17 of litigation. Dr. Kuehn's measurements, as you will see,
18 are unreliable, and he admitted his temperature measurements
19 were unreliable. Dr. Settles measurements show the air
20 coming out of the blanket being 33 degrees celsius which --

21 THE COURT: That's a lot lower than -- I don't
22 know what that is.

23 MR. ASSAAD: That's lower than body temperature.
24 That would be cooling the body temperature.

25 THE COURT: Well, wherever it's measured.

1 MR. ASSAAD: I mean, as the body temperature is 37
2 degrees celsius. If the air is coming out at 33, it's not
3 going to have a warming effect, that's the first law of
4 thermodynamics.

5 THE COURT: So he measured it coming out of the
6 blanket or he measured coming out of -- in the air
7 somewhere?

8 MR. ASSAAD: He measured -- he put a thermocouple
9 right at one millimeter away from the blanket and measured
10 it at 33 degrees celsius. That doesn't make sense. That
11 cools the patient down. That goes against --

12 THE COURT: Who did that?

13 MR. ASSAAD: Dr. Settles. So I don't think this
14 Court can rely on the measurements that defendants has taken
15 during the litigation.

16 JUDGE LEARY: Do you have any ideas to what the
17 temperature of the operating room was set at?

18 MR. ASSAAD: In Dr. Settles?

19 JUDGE LEARY: Yes.

20 MR. ASSAAD: Yes, actually. It wasn't an
21 operating room. It was a warehouse bigger than this. They
22 created a fake bed, a fake ventilation system, and it was
23 open on all sides, it wasn't temperature controlled. And so
24 the answer is I think the temperature was around I want to
25 say 50 or 60 degrees or 70 degrees.

1 THE COURT: 50, 60 or 70?

2 MR. ASSAAD: I'm not sure, I'm --

3 THE COURT: In that general range?

4 MR. ASSAAD: It was not controlled. And in fact,
5 on a couple of occasions they had to re-do the test because
6 of the excess humidity that was disrupting the flow.

7 THE COURT: What about Dr. Elghobashi, what was
8 his ambient temperature?

9 MR. ASSAAD: His ambient temperature was 59
10 degrees.

11 THE COURT: And was that a standard operating room
12 temperature?

13 MR. ASSAAD: That's based on standard operating
14 room temperature that's done by ASHRAE and it's been very
15 consistent, and, in fact, I don't think the defendants are
16 arguing the ambient temperature.

17 I kind of went way ahead in my PowerPoint
18 presentation so I'm going to go back a little bit to where I
19 was going. And, again, this goes to the weight, and the
20 case law is very clear.

21 JUDGE LEARY: Let me ask you about this. I'm
22 looking at an excerpt out of the Gold case in Minnesota
23 Supreme Court case and it says, in part, foundational
24 reliability requires the proponent of a test to establish
25 that the test itself is reliable, and I would assume that to

1 be the methodology is reliable, and then it's administration
2 in a particular instance can form to the procedure necessary
3 to ensure reliability.

4 You keep on saying that -- I think the second half
5 of that statement which Gold I believe stands for the
6 proposition that both parts of that statement are for the
7 Court to evaluate, but you're suggesting that the second
8 part, that is, the administration of the test or the
9 administration of the particular methodology whether or not
10 it conformed to procedure necessary to ensure reliability,
11 that's for the jury?

12 MR. ASSAAD: No, I'm not saying that, Your Honor.
13 The numbers and the equations used for the methodology,
14 whether or not they used the right boundary conditions, that
15 goes to the weight. Whether or not the methodology CFD is
16 correct, undisputed. The second part I think you're
17 referring to is whether or not the expert properly used the
18 methodology.

19 JUDGE LEARY: Put the correct input in.

20 MR. ASSAAD: Huh?

21 JUDGE LEARY: Put the correct input in.

22 MR. ASSAAD: Put -- not the correct input, the
23 numbers could be disagreed upon. That's what the jury
24 decides. Just like one expert says it's 33 degrees, one
25 expert says it's 28 degrees, our expert says it's another

1 thing. That is for the jury to decide. The methodology
2 that was used -- for example, our concern with Dr. Abraham
3 is not the CFD but the methodology and whether or not it is
4 reproducible is our motion to exclude for Dr. Abraham.
5 Whether or not the CFD methodology, which Memarzadeh has
6 used and all the stuff that he cited in his report, he used
7 the exact same -- he identified the methodology and he
8 followed the methodology, and I think that's one or two
9 going for.

10 With respect to the numbers, I think if he has a
11 reasonable basis for the numbers, which is, in this case,
12 3M's own internal documents that they say, and he does the
13 calculation off of those numbers, and they're not very
14 difficult calculations, I understand 3M agrees with them,
15 but that is for the weight -- it goes to the weight, not to
16 the admissibility. I hope that answers your question.

17 JUDGE LEARY: Well, I think it does, but it begs
18 this question, if this is a repeatable exercise, why not do
19 it in an operating room? Why not -- instead of relying just
20 on the computer fluid dynamic model, why isn't it done in an
21 operating room where you have the same parameters, you've
22 got a 59 degree operating suite, you've got the same level
23 of equipment, you know, the same assumptions that you did on
24 the computer model, why not do it in the actual operating
25 room?

1 MR. ASSAAD: Because the feasibility. That's what
2 CFD is for. To do this study in an operating room, number
3 one, plaintiffs would have to rent an operating room from
4 one hospital, which I don't know how much that would cost,
5 probably would be in the millions of dollars to take away an
6 operating room.

7 JUDGE LEARY: I suspect that the CFD model was
8 pretty expensive too.

9 MR. ASSAAD: But to do the PIV analysis -- we're
10 not talking about taking temperature measurements to show
11 turbulence. We're talking about particles, what happens to
12 particles. That's what Memarzadeh did. And Memarzadeh did
13 not go -- there, the guy they referred to as relying upon --

14 JUDGE LEARY: I'm really talking about, for
15 instance, the 106 degrees. Instead of relying on what you
16 believe to be the proper interpretation of 3M documents, why
17 aren't you measuring that with an actual Bair Hugger being
18 used in an actual operating room with the typical operating
19 room equipment, the typical number of persons present in an
20 operating room? Why not do it that way and find out what
21 the temperature is, whether it's 106 degrees or not?

22 MR. ASSAAD: Because we know that it was
23 106 degrees from the internal documents and we could plug it
24 into mathematical equations --

25 JUDGE LEARY: You're going around in circles. It

1 seems to me it could be reproducible. Cost aside, and I'm
2 not sure if the cost is comparable or not comparable to your
3 CFD.

4 MR. ASSAAD: Well, of course it could be
5 reproducible, and that goes to the admission of
6 Dr. Elghobashi's report. And if they want to go in and
7 argue to the jury that the number 106 is wrong, that goes to
8 the weight.

9 JUDGE LEARY: I'm concerned about the law that
10 says you have to look at the science in terms of a real life
11 application, that's what I'm concerned about.

12 MR. ASSAAD: Well, I'll go later on to get to the
13 real life applications of CFD in the world and, of course,
14 Memarzadeh used it too -- which all operating rooms are
15 designed after without doing a test of particles, and this
16 is at the NIH, because of the difficulty of monitoring
17 particles. Taking measurements does not tell you what
18 happens to particles. Particles are dealing with
19 turbulence, and I'll explain turbulence in a little bit, and
20 I think that might help you understand what was done in this
21 case.

22 CFD is a test. And the Seventh Circuit said a
23 mathematical computer model is a perfectly acceptable form
24 of test. It relies on engineering principles, Newton's
25 second law, fluid dynamics, heat transfer, Navier-Stokes,

1 Lagrangian and Euler. These are all accepted, generally
2 accepted principles in engineering. None of what
3 Dr. Elghobashi did relies upon Augustine.

4 THE COURT: So this all stands for the proposition
5 that computer modelling can be admissible?

6 MR. ASSAAD: Yes.

7 THE COURT: Right. There's really no doubt about
8 that. How in a particular case can the -- how do you -- how
9 would the -- how do you validate the code for a CFD model?
10 Because without -- I mean, right?

11 MR. ASSAAD: The code has to be --

12 THE COURT: You can't say computers come in, you
13 know, you've got to --

14 MR. ASSAAD: The code has been validated, and the
15 code is validated by studies. And Dr. Elghobashi cited
16 those studies in his report and which is ironic because
17 Dr. Abraham did not cite any studies to validate his code.
18 The way validation works is you validate -- I think Your
19 Honor understands --

20 THE COURT: Right.

21 MR. ASSAAD: Yes, you're a hundred percent
22 correct. What they do, and I'm going to -- I actually have
23 20 slides that talk about the validation of the code that
24 Dr. Elghobashi uses. I was going to go through them one by
25 one because it's kind of tedious, but I can show you a few

1 to show you how code is validated. But what they do is they
2 go and they do -- they think of a model, like the turbulent
3 flow through a cylinder and they'll run the code and then
4 they'll go attach a -- test the results, and not just one or
5 two data points. They go to look at all of the data that
6 was collected of a similar experimental model, identical
7 experimental model, and they'll run a graph, and they'll
8 show you --

9 THE COURT: Wait, did Dr. Elghobashi do all this?

10 MR. ASSAAD: No, he relied on the code that's
11 already been validated.

12 THE COURT: Okay. All right. So then you relied
13 on the code that's already been validated which puts the
14 emphasis then on the inputs.

15 MR. ASSAAD: And there's another way to validate
16 -- I'm sorry, I didn't mean to interrupt, and I know I did
17 last time I talked, and I apologize. I thought you were
18 finished. Are you done?

19 THE COURT: I'm afraid -- you know, I do the
20 interrupting and you get blamed for it, so I apologize for
21 that.

22 MR. ASSAAD: Another way code can be validated is
23 by -- there's three different types of CFD. There's RANS
24 Model, LES and DNS. DNS is what the -- what basically --
25 it's the highest level. It's what Dr. Elghobashi spent a

1 lot of time on. He uses it for doing military work for the
2 Department of Defense, Department of Energy. And I really
3 want to bring him here. He's a fascinating guy. The stuff
4 he's working on is high level. He's working on making an
5 aircraft carrier going 90 knots per hour in the ocean with
6 the Department of Defense.

7 THE COURT: You're all excited now. Just pretend
8 you're not an engineer. But anyways, you could also
9 validate the code by using DNS because DNS, direct numerical
10 simulation, is actually more accurate than experiments
11 because experiments have error. Experiments have error of
12 up to ten percent by taking measurements. DNS is 100
13 percent accurate. And engineers, the Department of
14 Military, Boeing, nuclear engineers all rely on CFD without
15 going in there and blowing up an atomic bomb, making 20
16 millionaire airplanes, or doing anything. It is the gold
17 standard for engineers.

18 And in *Zurn, In Re Zurn Plumbing*, this Court has
19 said, The issue here is similar to the one addressed in
20 *Quiet Technology D.C.* There an expert used a reliable
21 method, computational fluid dynamics, but the parties
22 disputed whether the expert put the wrong information into a
23 computer program that he used to compute his results. The
24 circuit court determined that when parties dispute the
25 specific numbers to be used in an otherwise reliable

1 scientific analysis, the alleged flaws are of a character
2 that impugn the accuracy of the experts' results, not the
3 general scientific reliability of his methods. The District
4 Court had therefore not abused it's discretion by declining
5 to exclude the experts' evidence under Daubert. Objections
6 to generally reliable scientific evidence go to the weight,
7 not its admissibility. This is not a close call. This is
8 not a close call.

9 And *Lapsley versus XTEK*, Defendant's argument
10 overlooks the fact that simulation is one of the most common
11 of scientific and engineering tools. Around the world
12 computers simulate nuclear explosions, quantum mechanic
13 equations, atmospheric weather patterns, and innumerable
14 other systems that are difficult or impossible to observe
15 directly. A mathematical or computer model is a perfectly
16 acceptable test.

17 And the Court goes on, We do not require experts
18 to drop a proverbial apple each time they wish to use
19 Newton's gravitational constant in the equation.

20 CFD is very accurate. We just talked about
21 validation. The methodology that Elghobashi --
22 Dr. Elghobashi has used, as well as Memarzadeh, as well as
23 other people in this field that he cited in his report, do
24 not require to go out and spend another millions of dollars
25 doing the particle tests.

1 THE COURT: No, the question is relevance because
2 you want to show that whatever was tested is sufficiently
3 relevant -- and is relevant and sufficiently helpful to a
4 determination of the issues at hand, and that's where if
5 it's either, okay, let's say he -- I hesitate to harp one
6 more time on this 106, but okay, so he takes it as 106,
7 fine, and then there's absolutely nothing wrong with the
8 model, there's nothing wrong with what he did, it's just
9 that -- and 3M has that document or whatever it is that says
10 106 but David tested, he came with a lower number, every
11 single person whose actually tested says a lower number so
12 then how do you argue that a test that assumes a number that
13 has been shown not to be a real number is relevant?

14 MR. ASSAAD: Well, first of all, with Dr. David,
15 he did a test on a faulty device and he put it in his
16 report.

17 THE COURT: But nobody tested and came up with
18 anything over 100.

19 MR. ASSAAD: 3M did. I'm relying on their
20 documents. They tested 106 degrees. The document I showed,
21 their operating manual. It's set at 42 degrees. I don't
22 know what more I could rely upon for the court. And it just
23 goes to the weight, Your Honor. They could argue that we
24 used the wrong number. They could get their engineer to
25 come in here and show different calculations, but it goes to

1 the weight of the evidence. It doesn't go to the
2 admissibility. We're talking about the methodology here.
3 We're talking about what Dr. Elgobashi did and whether the
4 methodology he used and whether he followed the methodology
5 according to the methodology.

6 No case has ever excluded CFD for lack of testing.
7 CFD is more accurate, as I said before, than real world
8 tests because it's a mathematical equation. And what's the
9 greatest think about this computational fluid dynamics test,
10 it has no confounders. It's Bair Hugger on, what happens;
11 Bair Hugger off, what happens? That's it. It's exactly to
12 show what happens to the particles which 40 percent of them
13 -- up to 40 percent carry bacteria happen when the Bair
14 Hugger is turned on.

15 Defense has argued we should do agar plates. And
16 the funny thing is they say we should do agar plates but
17 then, Mr. Gordon, when talks about the Avadan case about
18 using -- about doing the agar plate with the end of the hose
19 argued, yeah, but we don't know what was between the end of
20 the hose and agar plates. No mater what we do, the defense
21 is going to say that's the methodology, that's the wrong
22 test. We could use agar plates and they will say, well,
23 Avadan used agar plates and that's not correct. You know,
24 we did CFD, we used their numbers, it's not correct. Again,
25 it goes to the weight, not to the admissibility.

1 And what Elghobashi does, it confirms what 3M
2 already knew in 2007. And by the way, I don't think this
3 has been discussed about this document about the reduced
4 potential of nosocomial transmission, but the date of this
5 document is before Dr. Augustine said anything publicly
6 about his allegations against the Bair Hugger. This
7 internal document is in 2007. If you look at hot air rise
8 campaign which is cited as a footnote in defendants'
9 opposition, that's 2010. This is before Dr. Augustine said
10 anything about the Bair Hugger. Al Van Duren, director the
11 clinical research, they knew it and that's why they're doing
12 prewarming, especially for orthopedic surgeries.

13 Also, 3M has also done CFD tests that haven't been
14 produced that they've kept under privilege.

15 The question by Dr. Elghobashi is different than
16 the question that was answered by Dr. Abraham. What do
17 particles do in turbulence flow? That was the question
18 answered by Elghobashi, not streamlines. Streamlines, and
19 everyone admits, all the engineers, that particles do not
20 follow streamlines. Particles have mass and they have
21 inertia. The streamlines that Dr. Abraham did have no mass
22 and no inertia. It's an imaginary study. It's an imaginary
23 picture.

24 Let me talk about turbulence for a little bit
25 because I think turbulence is one of the most difficult

1 theories to understand, and I'm pulling off a lecture that
2 Dr. Elghobashi has given and he let me borrow his slides
3 that he explains to first-year students at the University of
4 Irvine. The end of a rocket is turbulent, that's obvious.
5 A jet engine has turbulence in it. The turbulent is where
6 you have multiple velocities going against each other. Wavy
7 motion in a ocean is not turbulent flow, but a ship going
8 through an ocean waves are turbulent flow.

9 As when we breathe in air, the air that passes the
10 epiglottis is turbulent and has different velocity, and the
11 reason I want to show this is, CFD is so accurate that they
12 could model an upper airway obstruction in which prior to
13 CFD what Dr. Elghobashi did, the success rate of the surgery
14 was around 50 percent. After modelling for these children
15 that have an upper airway obstruction, the successful rate
16 of the surgeon was 100 percent. That is how accurate CFD
17 modelling is.

18 Again, laminar flow, which we talked about a lot
19 which we like to call directional flow, laminar flow doesn't
20 exist in an operating room. The air is moving too fast.
21 From an engineering standpoint, it doesn't exist. From a
22 marketing standpoint, it exists. So that's the difference
23 between laminar flow and turbulent flow.

24 Reynolds. Reynolds was the first to kind of
25 quantify turbulent flow, and it shows the difference between

1 laminar, transitional and turbulent, and as you can see,
2 what they is stick a dye through water, and as they increase
3 the flow, they want to see what happens to the dye, and you
4 would just expect the dye to follow the path of the water.

5 Well, what turbulent flow does, it makes that dye
6 go up and down. It changes the velocity. It's no longer a
7 horizontal uniform velocity. There are different vectors in
8 the velocity, and as you see, as the increasing the Reynolds
9 number or the increasing flow along that tube, the dye in
10 the tube starts doing some crazy things. It creates
11 turbulence. It starts going backwards against the flow. It
12 does -- that's a circular flow. This is what turbulence is.

13 Turbulence is when you have multiple velocities.
14 These are called eddies, and that's how you hear large
15 eddies simulation. Large eddy simulation is where you model
16 the large eddies, the large turbulence, and these are going
17 to have an effect on particles and flow, and depending on
18 intensity, it affects the operating room.

19 As you increase the Reynolds number, you increase
20 the eddies. Now for the operating room that we modeled,
21 it's about 9,000. 9,000 is a decent size Reynolds number,
22 and it causes multiple turbulence as you'll see in the
23 following as I go forward.

24 Now, you have a spectrum of turbulence, and I
25 might just skip that because it is very complicated, but I

1 bill try to explain it if you would like me to try to
2 explain the large-eddies, but what we have is a scale at the
3 bottom, and as kinetic energy increases, then the eddies get
4 larger and larger, and that's what K is, the turbulent
5 kinetic energy, TKE.

6 I like this one because everyone thinks of
7 turbulence as shaking. When you get in an airplane, we are
8 going to be approaching turbulence, but the air around an
9 airplane is always turbulent. The Reynolds number is way
10 too high, but what's interesting, when you start here on
11 bumpy flights and you get large eddies, we are talking about
12 larger than the airplane, and it causes turbulence, or it's
13 larger than the fuselage. No plane has ever crashed as a
14 result of turbulence, so that's a good thing to know.

15 Large eddies simulation relies on these equations
16 called the Navier-Stokes equations, and you'll hear about
17 them a lot because the difference of what our expert did and
18 Dr. Abraham did is how they manipulated or what was used
19 with the Navier-Stokes equation and what was actually
20 solved, and Navier-Stokes equations have been going on by
21 Navier and Stokes from the 1800s.

22 The impossibility of solving the complete
23 Navier-Stokes equations led to the following: Werner
24 Heisenberg, the noble laureate, at age 31 was asked, What
25 would you ask God given the opportunity, and his reply was,

1 When I meet God, I am asking to ask him two questions: Why
2 relativity and why turbulence? I really believe that he
3 would answer only to the first.

4 According to Richard Feynman, the noble laureate,
5 the most important unresolved problem of classical physics
6 is turbulence, and that's why the invention of the super
7 computer made a difference. Since 1980, super computers
8 allow the type of work that Elghobashi and others in his
9 field would do, and what it does is, the Navier-Stokes
10 equations cannot be solved by hand. They can't be solved if
11 it's an open -- it's an open equation.

12 It is an equation that the way the super computers
13 solve it is actually by literally doing an algorithm and
14 putting in number after number in each of the grids of the
15 cells, which we'll talk about later, so that the numbers
16 match at the nodes. So that's why it's intensive. That's
17 why it takes two million CPU hours to run what we did in an
18 operating room because it's actually just doing a
19 convergence.

20 It's putting numbers in and see what the results
21 are and so they all match, and they say here's the final
22 result, and that's why it's very computer intensive, and
23 that's why it's very expensive, depending on the quality and
24 the type of test you run. You run RANS, which is the lowest
25 level, very cheap. If you run DNS, it's very expensive, but

1 DNS has its limitations, for example the size.

2 And this is the difference between RANS, LES and
3 DNS. DNS solves all the equations, all the equations for
4 the Navier-Stokes. Large eddy simulations models the small
5 eddy, and that's what both sides did and then RANS, and this
6 is the difference in the results between a DNS and a RANS.
7 I can go through the validation studies if you'd like.

8 It has been validated. There is no dispute. I
9 don't think there's a defense that the studies that
10 Elghobashi has cited regarding the validation of a code, but
11 I'd be happy to go through it if the Court likes me to go
12 through it.

13 THE COURT: It's up to you.

14 MR. ASSAAD: Okay.

15 JUDGE LEARY: Let me be clear. Are you aware of
16 whether or not the defense challenges the reliability or
17 authenticity of the code?

18 MR. ASSAAD: They've mentioned it here and there.
19 Mr. Blackwell said the code was unvalidated. I didn't hear
20 much regarding, from Peter Goss. They've put some stuff in
21 their opposition regarding validation. Their expert tried
22 to say it wasn't validated, but if you have any question
23 from the Stanford code, which is one of the leading
24 universities regarding turbulent flow, one of the people
25 that has been, that is cited, a guy by the name of Mahesh,

1 which is Stanford PhD, is actually now at the University of
2 Minnesota.

3 And if you have any questions about whether or not
4 the code that he's worked on or what this all means, I
5 welcome you to call him up and say, is the code validated
6 for this type of flow, because it is. The complexity that
7 this LES CFD is used for is much more than what it's used
8 for in this case.

9 They use it for combustion and all different types
10 of flow, and that's another thing. If a CFD has been
11 validated for a more complex flow, that's called a
12 benchmark, and when you have a benchmark, that's validated
13 for anything that is less complex than the flow that's used
14 here, and I will go through it real quick.

15 And again, the defense is trying to -- doesn't
16 distinguish between validation and testing. They've thrown
17 up the NASA thing and said you need validation, and the
18 plaintiff hasn't validated this code, but according to NASA,
19 the page discusses validation assessment which focuses on
20 the message for the validation of a CFD code for a
21 simulation.

22 So this is a code. This was from 1982, and again
23 I'm not going to go through it. I'll give you my slides,
24 but Mahesh is up here at the University of Minnesota did a
25 study and tested it towards published data. You can

1 validate a code by actually going to do the tests, or you
2 can validate it for tests that have been previously done.
3 In this case it was as validated for previously done. No
4 noticeable difference observed, and this was a laminar flow
5 with recirculation.

6 And again, this is Mahesh. This is what it looks
7 like when you do a validation study, and this is what you
8 don't see with Dr. Abraham and what he used. When you
9 validate a code, and this is the code. You see data points,
10 and then you see lines going through, and you calculate the
11 experimental error, and this code is well validated for this
12 type of test.

13 Again, this was not compared to a DNS model in
14 2004 by Mahesh, and it shows less than a 2 percent
15 difference in the mean and velocity and drag. It tells you
16 what the error rate is between the code and the experimental
17 results, and when it is left is five percent, and you don't
18 know which one is right because the test could be off by
19 five percent as well. So if it's within five percent, it's
20 a validated code.

21 And here's more validation. The code is
22 validated. Here's another example of testing of the code,
23 the validation, where they have the real data points and
24 what the code is showing, and the lines match up pretty
25 close, if not perfect, and again, another validation to --

1 and these are, and by the way, validations are studies.
2 They're usually published. So what is used? That's why you
3 always see them published in the literature.

4 And this series of questions, ask Mahesh. He is
5 here at the University of Minnesota. He has worked on this
6 code.

7 THE COURT: You just have to know that that's
8 completely illegal, right?

9 MR. ASSAAD: We could get a consulting expert, I
10 guess, if you have a question regarding --

11 THE COURT: Yeah, no.

12 MR. ASSAAD: I did not know it was illegal.

13 JUDGE LEARY: You have provided a very good, very
14 provocative argument for your position, but here it is so
15 technical, it is so scientific, it is so -- it's beyond my
16 capacity as a lawyer and a judge to fully comprehend it, and
17 yet, we're being called upon to determine whether or not it
18 is scientifically reliable.

19 And then you argue, well, it's really -- at some
20 point it's not for me as a judge or any other judge to
21 decide, it's for the jury to decide. Then you circle back
22 to the argument. Why are courts and why would a court and
23 why would a jury decide an issue that is so complicated and
24 if it otherwise lacks merit has not been endorsed by the
25 scientific community?

1 That's a fundamental struggle that I have because
2 in all honesty, and I think there is case law to support it.
3 Law doesn't drive the science. Science has to drive the
4 law, and when you're asking jurors and when you're asking
5 judges to engage in these types of scientific fact finding,
6 I don't think you get the most authentic results through
7 this process.

8 And that's why I think courts circle back to the
9 fact, you have got to rely on the scientists. You've got to
10 rely on what is considered to be reliable science among
11 competent experts. It has got to be generally accepted by
12 the scientific community.

13 MR. ASSAAD: There is no dispute, Your Honor, even
14 under Frye Mack that the methodology used by Elghobashi is
15 generally accepted. I don't hear anyone saying that CFD is
16 not generally accepted.

17 JUDGE LEARY: But that only tells us part of the
18 story as to whether or not the plaintiffs' claim is reliable
19 and their science is reliable.

20 MR. ASSAAD: Of course, it -- you know, Elghobashi
21 is not going to come in and testify that bacteria causes
22 infection. That's outside of his expertise. What he's
23 going to come in and say -- by the way, some of their
24 experts agree that the Bair Hugger can increase particles
25 over the surgical site, their engineer experts because they

1 are based on generally accepted science.

2 When you turn the Bair Hugger on it affects uni
3 directional flow, and you'll hear, what is the purpose of
4 the uni directional flow in the operating room? The
5 purpose, and we'll all agree on it, is to put clean air,
6 filtered air, the air is filtered twice. There is a pre
7 filter and then another filter before it enters the room,
8 over the surgical site to protect it from bacteria.

9 And Dr. Elghobashi is using general accepted
10 principles Navier-Stokes equations, Newton's second law,
11 heat transfer, fluid dynamics to say when you turn this
12 thing on, this is what happens based on the science,
13 generally accepted science.

14 THE COURT: Okay. So he says this is what happens
15 when you turn this on. Assuming that the assumptions that I
16 put in are correct, this is what happens, and so the
17 preliminary admissibility question has to do with whether or
18 not there is sufficient correspondence between what he put
19 in and what happens in the real world.

20 And I understand that you have good points about
21 how it does correspond sufficiently to what happens in the
22 real world. So but all he can say is, if this and this and
23 this, then this.

24 MR. ASSAAD: Yes.

25 THE COURT: Okay.

1 MR. ASSAAD: And as we talked about, the weight of
2 the evidence versus admissibility. They're of course going
3 to say, you know, that it's not the temperature, you know.
4 But, of course, their experts also testified against each
5 other, saying the temperatures they use are wrong so.

6 THE COURT: Just to isolate. What the question is
7 for the Court, it's not -- at this time it's just whether
8 the, I guess it comes down fundamentally to whether the
9 temperature is -- whether the inputs were sufficiently
10 connected to the facts of this case, that the running of the
11 tests that he did, assuming that those tests are accurate
12 and reliable and rock solid, would be of use to a finder of
13 fact in deciding whether the Bair Hugger can cause
14 infection.

15 MR. ASSAAD: I think *Daubert* is more liberal than
16 that, Your Honor. I think *Daubert* is what the courts say,
17 that the boundary conditions can be disagreed upon and the
18 defense could point with all their evidence they want at the
19 jury and say, he used 106. We think it's only supposed be a
20 100 or 97 or 75, and the jury is supposed to decide what is
21 the correct temperature.

22 THE COURT: That's what I asked you what
23 Elghobashi had to say, if anything, about the utility of his
24 test if the temperature was not exactly that.

25 MR. ASSAAD: There is still utility. He will

1 testify -- remember, this is general causation. The
2 question here is, can the Bair Hugger cause bacteria to
3 reach the surgical site? And when we get to the case
4 specifics, we'll deal with the individual --

5 THE COURT: I know Elghobashi says if it's at 106,
6 here's what happens, and yes, that would cause all this
7 disruption, and from there you go to the disruption to the
8 particles, which are a proxy for bacteria or even bacteria
9 into the surgical site. Doesn't take very many, and you're
10 off to the races.

11 MR. ASSAAD: We've been saying that a lot today.
12 I understand, Your Honor. I think we could say more than
13 that because we're looking at engineering principles here.
14 Can he say, we'll be able to testify it's at 105? He could
15 say based on his education, training and experience and the
16 model and the studies that he's done, 105 would probably be
17 the same thing, and there will probably be a limit that he
18 could say more than likely than not this temperature will
19 cause it.

20 THE COURT: But I'm asking what's in his report.
21 How much tolerance is in his report?

22 MR. ASSAAD: While my colleagues are looking that
23 up, I will -- if I could continue. I have to find it
24 exactly in his report, if you give me --

25 MAGISTRATE JUDGE NOEL: While you're doing that,

1 didn't he also get cross examined about this, about this is
2 the temperature along the drape. Is that what we're talking
3 about?

4 MR. ASSAAD: Yes.

5 MAGISTRATE JUDGE NOEL: And wasn't that a subject
6 of cross-examination?

7 MR. ASSAAD: Yes, vigorous cross-examination.

8 MAGISTRATE JUDGE NOEL: Was there a range where he
9 talked about, when you get to below a certain temperature
10 this won't happen?

11 MR. ASSAAD: I don't think that was ever asked by
12 him in the deposition, but based on, I mean, when it comes
13 time for case specific and they want to say it's a different
14 temperature or set at a different temperature, they can ask
15 him the questions, and he'll either run a new test or rely
16 on the model, but it's based education, training and
17 experience and calculations.

18 THE COURT: Okay. I think we probably beat that
19 one.

20 MR. ASSAAD: So the defense tried to make this
21 thing about a thought experiment. This is a thought
22 experiment, and they've shown you a part of the deposition.
23 I asked him on cross-exam, because, again, he has never had
24 a deposition before. It's the first time. He, you know,
25 he's from a different country, you know. I want to clarify

1 what he meant when he says I thought about it a lot.

2 He says, I thought about it a lot, and I asked
3 him, And the calculations when you talked about, you thought
4 about it a lot. Is that the boundary condition?

5 That's regarding the temperature, but regarding
6 the mass loads, it's conserved. It means on a flow, the air
7 mass flow rate that leave the blower has to come out along
8 the drape because the drape covers everything. That's no
9 assumption. Okay.

10 The temperature, yeah, I did some estimate
11 calculation.

12 Okay. You did calculations?

13 Not a computer. Hand calculations, and they're
14 mathematical calculations.

15 And those calculations were based on your
16 education, training and experience?

17 Yes.

18 And Dr. Elghobashi, which is enough. He describes
19 his calculations by hand, actually went back after the
20 deposition and did the calculation or made a copy of the
21 calculation or he did them based on what he did on a piece
22 of paper, because they're very simple for him, and they're
23 like Newton's law, and he provided these calculations.

24 And he provided these calculations, and we
25 provided them to the defense of how he calculated the air

1 from the exit temperature of the blanket, which comes at
2 106 degrees, to the air that was used in the boundary
3 conditions.

4 THE COURT: Okay. That's good. Thanks. Nobody
5 ever measured that air at 106 but --

6 MAGISTRATE JUDGE NOEL: 106, as I understand it,
7 is something he took from defendants' video of saying what
8 temperature was.

9 MR. ASSAAD: Defendants video documents their
10 operating manual. It's defendants' number. It's not our
11 number, you know, and not only that, the number that they
12 used for Dr. Settles of 33 makes it cooling the patient.
13 The numbers don't make sense. It has to be warmer than 37
14 at the degrees, otherwise it's not going to warm the
15 patient.

16 THE COURT: Okay. We have got to move to a
17 different topic.

18 MR. ASSAAD: Again, the air in the boundary
19 conditions goes to the weight of the evidence, not
20 admissibility. Abraham used the same temperature, not
21 inconsistent with any facts, and the source of the
22 temperature, again, and I don't know if Judge Noel was here,
23 but 3M's internal documents.

24 This is what Elghobashi did, and I don't think
25 you've seen the video. This is when the Bair Hugger is off,

1 and this is the air flow of what occurs with a uni direction
2 national ventilation system. As you can see, this is not
3 temperature. This is velocity. Velocity is faster. The
4 darker it is, that's where the velocity is faster.

5 THE COURT: It's going down to the floor and is
6 blowing stuff up.

7 MR. ASSAAD: Of course, when it hits the floor,
8 but look at the operating room table and what occurs.

9 JUDGE LEARY: Can I ask a question? Is there any
10 assumption here as to the presence of other equipment or
11 people?

12 MR. ASSAAD: There are people in the operating
13 room. There's an anesthesiologist.

14 JUDGE LEARY: It has to count for four.

15 MR. ASSAAD: Yes, you'll see in the following
16 pictures. Again, Dr. Abraham did not account for people,
17 and this is where the Bair Hugger turned on, and you'll see
18 over time as the heat goes around the edges, not where Peter
19 Goss says it's coming out of. The heat is going down the
20 edges down through the below, and you start seeing it
21 change, and you start seeing convection currents or changes
22 of velocity going up.

23 This a real world model using generally accepted
24 mathematical principles.

25 THE COURT: You stopped it before it got to the

1 patient.

2 MR. ASSAAD: Excuse me?

3 THE COURT: You stopped it before it got to the
4 patient.

5 MR. ASSAAD: I'm sorry. I have a bunch of slides,
6 but this shows temperature, if you want to see the
7 temperature the change in temperature, I think.

8 JUDGE LEARY: Let me interrupt just for a moment.
9 To Judge Ericksen's point, just before you replayed this,
10 from this depiction do we understand that there's a change
11 in turbulence over the patient?

12 MR. ASSAAD: No. I think the change in
13 turbulence, which I'll show in a picture later on, which I
14 think during the general cause, there was a turbulence
15 picture that Ms. Conlin put up that had the red, the
16 difference in turbulence between the Bair Hugger on and the
17 Bair Hugger off.

18 JUDGE LEARY: And I'm sure you'll correct me if
19 I'm misinterpreting this, but I thought the model was for
20 purpose of depicting the turbulence that occurred over the
21 patient that would result in particulate being in that area,
22 but that's not shown here.

23 MR. ASSAAD: That's just showing the change of
24 velocity that occurs when you turn the Bair Hugger on of the
25 air around the operating table.

1 JUDGE LEARY: Thank you.

2 MR. ASSAAD: This will just show the change in the
3 temperature, and I'll skip what happens when the Bair Hugger
4 is off. I'll just show when the Bair Hugger is on, and as
5 you can see, as everyone knows, hot air rises, and they et
6 buoyancy currents that carry particles, and on top of that,
7 you have the intensity of the turbulence that's also moving
8 the particles up, and you'll see that in the following
9 slides.

10 And what's interesting is, you have the particles
11 go up over the surgical site by turbulence and by velocity
12 factors, and the uni directional downward flow pushes that
13 right onto the patient, and you'll see that when we do the
14 particle slides. This is the intensity, the difference in
15 turbulence over here, and you can see how the turbulence
16 intensity significantly increases when the Bair Hugger is
17 off, which is A, and when the Bair Hugger is on, which is B.

18 And turbulence is the question here regarding
19 particle flow. That's what this study very computational
20 intensive. It is not streamlined. It's turbulence.

21 And what Dr. Elghobashi did here was, he put three
22 million skin squames, 10 micron particles on the floor about
23 two or three centimeters off the floor, and he color coded
24 them one million red, one million green, one million yellow,
25 so he could determine where are the schemes coming from.

1 And you pick 10 micron squames, and I think
2 everyone knows that's a conservative approach. No one
3 disputes the 10 micron particles that he used, and in fact,
4 in the Memarzadeh, he also used 10 micron particles, but he
5 used RANS instead of LES, and you see with the Bair Hugger
6 on, you see the surgical site, and around the surgical table
7 free of particles.

8 This is not an animation. This is a real world
9 model of what happens based on generally accepted
10 mathematical principles, and again, this is where the Bair
11 Hugger is on. I wasn't sure which one I pressed, and what
12 is interesting, as you will see, and all parties agree,
13 Dr. Abraham and Dr. Elghobashi, everything in the operating
14 room makes a difference. The people make a difference.

15 The people have also have thermal plumes that
16 create, and that's what Elghobashi did here. The way he did
17 his study was so advanced compared to Dr. Abraham. What he
18 did first was model the operating room with the
19 measurements. Then he ran the operating room with no heat
20 properties for the people, and he calculated basically for
21 80 seconds air through the operating room.

22 And as you can see here, the particles go over the
23 surgical table and mostly the red particles, and the reason
24 why they are mostly the red particles is because when you do
25 an operation, usually two people on one side and one person

1 or the other side for most orthopedic surgeries, and you
2 have the anesthesiologist sitting at the head.

3 There's more turbulence and more, the convective
4 currents are going to be blocked with the people on both
5 sides, and that's why we see the red being more predominant
6 over the yellow and green.

7 THE COURT: Let's say you only have about five
8 minutes left to talk.

9 MR. ASSAAD: I only have a few more slides.

10 THE COURT: Just spend the time however you want.

11 MR. ASSAAD: I'll go really quick. I just -- this
12 is what you've seen before, but what also Dr. Elghobashi did
13 is, he put boxes around certain areas of the operating room,
14 side Table 1, side Table 2, the surgical site where the knee
15 is and the whole surgical table, and he graphed it.

16 And the importance of that is we're, not just
17 saying that the Bair Hugger, the particles have to get into
18 the wound during the time, but they could also contaminate
19 the surgeon's hand or where the implant is on the side
20 tables when they open it. Bacteria gets there and
21 contaminates the implant.

22 And this is what happens when the different amount
23 of squames that are shown. So when you look on side
24 Table 2, you see that in about 15 to 20 seconds, you have
25 about 15 to 20 number of skin squames. If you look at the

1 whole surgical table, you see about 1500 skin squames as a
2 result of the Bair Hugger being turned on in about 20
3 seconds.

4 We're not saying all of those are bacteria, but we
5 also agree that a certain percentage of that is bacteria
6 based on the infectious disease experts, and over the knee
7 in about 25 seconds, you see 200 or 250 skin squames over
8 the knee as a result of the Bair Hugger turned on. When the
9 Bair Hugger was off, free and clear.

10 Again this is just proving what the defendants
11 knew about back in 2007. 3M conflates biological
12 plausibility with the mechanism of exposure. This is a
13 mechanistic study. It's an engineering study. How does the
14 bacteria get to the wound or to the implant? And it's done
15 through engineering, which is generally accepted in the
16 community.

17 The concept of biological plausibility asks
18 whether the hypothesize causal link is credible in light of
19 what is known from the science and medicine, about the human
20 body and potentially offending agent. No dispute here. The
21 bacteria is the biological agent. The biological
22 plausibility question is simply whether the offending
23 agent's bacteria causes the injury infection. Undisputed it
24 does.

25 Biological plausibility is not reasonably in

1 dispute. There is a general consensus, if not mere anatomy,
2 that bacteria can cause joint infection. How does the
3 bacteria get there? The generally accepted scientific model
4 based on Navier-Stokes equations, Newton's second law and
5 many other equations that are hundreds of years old that
6 have been solved by a super computer show how this is
7 mechanistically possible or probable that the Bair Hugger
8 causes, that Bair Hugger puts bacteria over the surgical
9 site.

10 If there's any questions?

11 MAGISTRATE JUDGE NOEL: I just have one. You
12 indicated that what we were watching was not an animation,
13 but it is a computer simulation generated by the arithmetic,
14 pardon the expression, that the computer does based on the
15 input that Dr. Elghobashi inputted. Is that a correct
16 statement?

17 MR. ASSAAD: Yes, 100 percent. It is a real live
18 model based on engineering principles. It's not an
19 animation that we hire someone to put together. This is
20 what the computer puts out based on the information that it
21 calculates, based on generally accepted engineering
22 principles.

23 MAGISTRATE JUDGE NOEL: But, again, but it is a
24 simulation in the sense that arguably if you had three
25 million of those color coded things and you threw them on

1 the floor in an operating room and turned on a video camera,
2 you would see the same thing, but this is a computer
3 simulation of that based on the algorithms that
4 Dr. Elghobashi put into the software that created that what
5 we're watching on the screen.

6 MR. ASSAAD: Yes. When you say three million,
7 that was best case scenario for 3M studies have been shown
8 and cited that between one million and nine hundred million
9 skin squames fall in a two to four hour period. So three
10 million was on the low end. He did that for two reasons.
11 Number one, best case scenario for 3M, and really the other
12 reason is the cost. If we had to track 20 million
13 particles, it would be, it would show it would exponentially
14 increase the number of particles, but it's just, it would be
15 computer time, and to use the computer, the super computers,
16 you have to be efficient.

17 MAGISTRATE JUDGE NOEL: Thank you. Thanks.

18 THE COURT: All right. We'll take a 10-minute
19 break.

20 (Afternoon recess at 3:02 p.m.).

21 (3:19 p.m.)

22 THE COURT: Please be seated.

23 MS. ZIMMERMAN: It was our sense that because the
24 initial motion was combined on engineering issues that
25 Mr. Goss has made in his presentation with respect to

1 Elgobashi, Buck, Dan Koenighofer and --

2 THE COURT: He already did that.

3 MS. ZIMMERMAN: He did that, and then I was just
4 going to add a few moments on Mr. Buck and Mr. Koenighofer
5 because that has not been addressed.

6 MR. GOSS: That is fine. I was just going to
7 respond to the argument about Elgobashi, but I can wait if
8 the Court would prefer.

9 THE COURT: All right. We have a question.

10 MAGISTRATE JUDGE NOEL: Just before you begin
11 though, Ms. Zimmerman, I asked a question earlier that after
12 conversing with the two judges during the break, I got
13 confused about what I thought the answer was, and so I'm
14 going to ask it again. It's my understanding based on what
15 I thought I heard the answer this morning is that all of the
16 plaintiffs in the MDL have suffered a deep --

17 MS. ZIMMERMAN: Deep joint infection.

18 MAGISTRATE JUDGE NOEL: Deep joint infection, and
19 the judges told me that they thought that only applied to
20 the plaintiffs selected for bellwether cases, but that
21 there's a range of infections that are not all deep joint
22 infections or periprosthetic joint infections. So the
23 answer is?

24 MS. ZIMMERMAN: The answer is almost all that I
25 know of are orthopedic periprosthetic joint infections. I

1 do believe that there are maybe a handful five or six cases
2 that have been filed by various folks involving a prosthetic
3 valve in a heart surgery because Bair Huggers are also used
4 in cardiac surgeries. I think that the focus has really
5 been on the implant of a prosthesis because of the nature of
6 biofilm and the ability of these small quantities of
7 bacteria to create an infection.

8 Unfortunately, because there are not just the
9 plaintiffs steering committee members, but there are many
10 hundreds of law firms that filed these cases, I can't speak
11 to every single one of the 4300 cases that are presently
12 pending before Your Honors, but I think the vast majority
13 are orthopedic cases involving deep joint infections and
14 certainly Judge Ericksen is correct that that was a
15 requirement with respect to the bellwether cases, so that's
16 all that we're talking about with respect to bellwethers.
17 Is that helpful?

18 MAGISTRATE JUDGE NOEL: Thank you very much.

19 MS. ZIMMERMAN: So I wanted to take just a brief
20 moment to speak to the motions brought against two of the
21 plaintiffs' expert Michael Buck and Dan Koenighofer, and I
22 think that we'll rest largely on our papers, but the rules
23 do not require that every expert that the plaintiffs or the
24 defendants call to provide testimony in this matter be a
25 walk-off, grand slam hitter, so to speak.

1 And so what we have offered by way of expert
2 testimony are a series of experts, seven at this general
3 causation stage, that can establish different pieces of
4 evidence that are appropriate and required for us to prove
5 or meet our burden.

6 Mr. Buck is at the University of Minnesota and
7 part of his job is to do particle testing and biological
8 sampling. And the experiment that he did and reflected in
9 his report were done prior to the testimony that we had from
10 the 30(b)(6) witness that agreed that every single study
11 that's been done to date shows that Bair Huggers create
12 particles over the surgical site at the time of surgery.

13 So Mr. Buck is certainly well-qualified to talk
14 about what he does as a matter of practice in his employment
15 at the University of Minnesota. Likewise, Mr. Koenighofer
16 is on the ASHRAE committee along with defendants proffered
17 expert on this Michael Kuhn from Canada, and his testimony
18 is really to talk about the environment of use before Your
19 Honors and the jury in this matter, and really the issue is
20 to some of the questions the Court has asked today about
21 what is the air flow rate like in an operating room?

22 There are minimum standards that are set by
23 ASHRAE, and Mr. Koenighofer would be offered to testify to
24 the jury essentially about what the environment of use is
25 and why air exchange rates and positive pressure and the

1 filtration system in the OR are necessary, based on his
2 training and experience. Neither of those witnesses are
3 offered to make the ultimate conclusion in this case, which
4 is does the Bair Hugger cause periprosthetic joint
5 infections as a general matter?

6 And, of course, under 702, expert testimony has to
7 be based on sufficient facts or data, and to the extent that
8 any of the facts may be in dispute, the comments to Rule 702
9 make specifically clear that those experts' testimony should
10 not be excluded by the Court in the event the Court finds
11 one more persuasive than another.

12 And this was recently, and I shouldn't say
13 recently, this was addressed square on in both the *Pipitone*
14 *v. Biomatrix* case out of the Fifth Circuit, 288 F.3d. 239.
15 And also in *Micro Chemical v. Lextron*. The citation is 317
16 F.3d., 1387, and that's a Federal Circuit case from 2003.
17 So in both of these cases stand for the proposition that the
18 Court is not to serve as a replacement for the adversary
19 system. So to the extent that there are data or facts that
20 are in dispute and, certainly, as we've been here for two
21 talking about what articles may say what and what the
22 interpretation of a particular figure or chart may be,
23 that's something that provided that the experts that have
24 been offered by each side have reliable methodology and are
25 appropriately qualified to opine on, that is something that

1 goes to the jury.

2 And with that, I will pass to -- are we going to
3 say anything about Dr. David right now?

4 We thought that we would combine all remarks with
5 respect to Dr. David at one time rather than break it into
6 two pieces. Mr. Goss.

7 MR. GOSS: Thank you, counsel. And just to be
8 clear the basis of our motion on the engineering experts or
9 the target is the general causation opinions. So, you know,
10 testimony about air flow rates, air change rates, we're not
11 challenging any of that. It's really the general cause
12 opinions that we're focused on because that's what the goal
13 of these two days is is to test the sufficiency of the
14 plaintiffs' general cause.

15 Evidence. And I just wanted to respond to a few
16 things on the CFD. For one thing, on the different
17 temperature measurements of the temperature data --

18 JUDGE LEARY: Let me see if I understand what you
19 just said, Mr. Goss.

20 MR. GOSS: Yes, sir.

21 JUDGE LEARY: Are you saying that the experts that
22 were commented upon by Mr. Assaad that how we as judges
23 choose to resolve the state of the evidence is really not
24 germane to the ultimate issue that has to be decided that is
25 whether or not Bair Hugger causes deep joint infections?

1 MR. GOSS: No, Your Honor. What I meant to say is
2 there are really two issues, one is the foundational
3 reliability under the Frye Mack standard of the evidence
4 that's being offered and if you get past that hurdle, then
5 the question is is it sufficient to meet the plaintiff's
6 burden of proof to establish general causation. So there
7 really are two thresholds not everything that the
8 plaintiffs' experts are saying really goes to the question
9 of causation. There are some contextual things such as do
10 you have 20 air changes per minute in an OR? That doesn't
11 really move the needle one way or the other in terms of
12 their general cause opinions, and so that's what we're
13 really focused on is the sufficiency of the evidence to
14 carry those opinions that will then be used to actually
15 support their claim of general causation.

16 So on the different -- the temperature evidence
17 that was discussed, there was mention of an internal 3M
18 document that had temperature readings and where that came
19 from is a particular ASTM test for warming blankets. The
20 American Society of Testing materials, there's actually a
21 test standard for making sure that your blanket delivers
22 heat the way you claim it does, and there's a specific test
23 apparatus. And it's a styrofoam bed that's about the size
24 of this table, maybe a little larger, and it has these
25 copper sensors in it that are imbedded in it to detect the

1 temperature.

2 And so what you do to run that test is you put the
3 blanket on face down, and you run it to see if you're
4 getting the temperatures that are consistent with your specs
5 that are in the operating manual. Okay. So that is
6 measuring the temperature of the air and the blanket coming
7 right out and capturing it in an insulated styrofoam test
8 apparatus.

9 What Dr. Elgobashi did was he was assuming that
10 temperature for this drape area on either side here. Okay.
11 So not directly under the blanket, but coming out of the
12 drape over the blanket from the shoulder all the way down to
13 the floor, and that's what his report says is that he
14 assumed 106 degrees and 53 feet per minute all along this
15 entire perimeter, and he didn't model anything else. The
16 that's what he committed to. He didn't leave himself any
17 wiggle room in his report to say, well, you can scale it
18 down, and you'll still have the same effect.

19 He did say in his general opinions appendix that
20 if you modelled with the 505 Bair Hugger, the same thing
21 would happen at a lower rate, but he didn't actually model
22 that. That's just what he says.

23 Mr. Assaad made a comment that I thought was
24 illuminating. He said all CFD is imaginary, and to a large
25 extent it is because when you're doing an operation you

1 don't have the surgeon standing like this. They're moving
2 around. They're cutting. They're doing things, and what
3 you see in the model the people are standing stock still,
4 and not all the elements are even there. There's no
5 anesthesia machine, for example, that would be --

6 THE COURT: I think that Mr. Assaad used that
7 phrase, "it's all imaginary," I think he used that in one of
8 your dreams. I don't think he used it in --

9 MR. GOSS: Did he not say that? Okay, I'm sorry,
10 I thought I heard it.

11 MR. ASSAAD: I could tell you how I used if you
12 want, Your Honor.

13 THE COURT: Did you use it? Did you use it?

14 MR. ASSAAD: I said the mass, their CFD guy used
15 particles air with no mass and no inertia and that's an
16 imaginary object.

17 MR. GOSS: Oh, okay. I must have misunderstood
18 him, but the point is that it is imaginary in the sense that
19 you don't have people moving around. That's undisputed.
20 And there's also the fact that he also said, well, the
21 beauty of CFD is that there are no confounders. Well, in a
22 real operating room, there are always confounders. There
23 are always people moving around. There are always people
24 generating air currents just like I'm generating air
25 currents with my movement right now. That's not reflected

1 in the CFD model.

2 And this is all significant because the case law
3 has said here's a case from Southern District of New York,
4 *Reed Construction Data v. McGraw-Hill Companies*, 49 F.Supp.
5 3d 385. The Court held "where very minor changes in
6 arbitrarily selected model parameters can entirely alter the
7 models conclusions, that model is insufficiently robust to
8 withstand scrutiny of Rule 702."

9 And then in the Second Circuit, *Wills v* -- I can't
10 read Mr. Blackwell's handwriting -- but this case, 379 F.3d
11 32, "to be reliable, data analysis must account for major
12 variables including confounding variables." Well, if you're
13 saying there's no confounders, then there's a problem with
14 the model.

15 And really the test for all this as I think I
16 alluded to earlier is one of foundational reliability. And
17 the judges don't have to be an engineer just like I don't
18 have to be an engineer. The Court can simply apply the same
19 test that was used just to determine the admissibility of
20 any piece of evidence and that is is it trustworthy and
21 that's what Daubert ultimately is about, is it trustworthy
22 given all the data that the Court has seen.

23 Dr. Elgobashi was in an operating room in Santa
24 Monica right here (indicating). He had the opportunity to
25 take temperature measurements. Now plaintiffs can throw

1 shade on all the measurements that all of our people took,
2 but they didn't take any of their own and why wouldn't they
3 if they're going to spend all this money on a CFD, wouldn't
4 you want to get it right?

5 And, finally, I'll just say that this Court would
6 be the first place in the world really if the CFD were
7 admitted as proof towards general causation to allow or to
8 endorse the idea that a CFD can be used to determine the
9 cause of an infection. That's never been done anywhere in
10 the peer reviewed literature. And plaintiffs cited cases
11 where CFDs have been admitted, and they certainly had been
12 admitted in many cases in a variety of circumstances. I
13 will note in the *Zurn Pex* case, the Eighth Circuit's holding
14 was simply affirming the District Court's discretionary
15 call.

16 But, ultimately, there's no case where a medical
17 mass tort has been decided based on a computer simulation.
18 And if that's what the plaintiffs are saying they have to
19 support general causation, well, it's so far over at the
20 left hand side of our schematic and the exploratory realm,
21 that it simply isn't enough to carry the weight of
22 establishing general causation. Thank you.

23 THE COURT: Mr. Goss, could you just -- the thing
24 that the plaintiffs keep coming back to is that they got
25 this 106 from your document. The document that Mr. Assaad

1 was working from is that the document? That's the one we're
2 talking about?

3 MR. GOSS: Yes, that's the one we're talking
4 about. Where he said he got it was from the You Tube video,
5 but it's essentially the same number.

6 THE COURT: So is that's the same whatever that is
7 and that says temperature of the blanket?

8 MR. GOSS: Right.

9 THE COURT: All right. Thank you.

10 MR. GOSS: Okay. Thank you.

11 MR. ASSAAD: Abraham is next, Your Honor.

12 THE COURT: Okay. So where are we?

13 Do you have -- do you want to make your motion to
14 exclude Abraham? That's where I'm thinking we are, but you
15 were --

16 MR. ASSAAD: Unless the Court has any questions on
17 Dr. Elgobashi, I'm going to move on to Abraham.

18 And just real quick on Dr. Elgobashi, I know it's
19 a very complicated CFD topic, and if this Court would like
20 him to come in, we'd be happy to bring him in if there's any
21 questions the Court would like with regard to understanding
22 CFD or any of the subject areas of the calculations that he
23 did because I know it's very complicated.

24 Moving forward to Dr. Abraham. Defendant admits
25 that Abraham failed to provide the underlying data, facts,

1 and equations in his expert report. His expert report
2 refers to no online videos or no published paper. And in
3 fact when he said he had a published paper, defendants
4 precluded plaintiff from asking any questions regarding the
5 published paper during his deposition. Even after the
6 opportunity to correct or have an errata sheet with any
7 questions I've had, he only put three things down on his
8 errata sheet to change anything or to add anything regarding
9 his testimony during his deposition.

10 I'm going to talk about seven factors very
11 quickly. His opinions are not relevant. He is not
12 qualified as an expert on particle movement and turbulent
13 flow. His report does not have any data to support his
14 opinions. His CFD model goes to being not reproducible, I
15 think that goes to the second prong that Judge Leary you
16 were talking about earlier.

17 Experimental methodology, his fault studies is
18 flawed and not reliable. He's not qualified to offer his
19 opinions outside his expertise basically commenting on the
20 medical literature, and his criticisms of Dr. Augustine and
21 his hot air rises is not rebuttal.

22 Undisputed facts. Dr. Abraham's model lasts only
23 1.2 seconds. He turns the Bair Hugger on and then he takes
24 his measurements and that's it, doesn't give it time to get
25 up to study state. It is no different than turning on a

1 heater in this room, raising the temperature by 20 degrees
2 for 1.2 seconds. It's not going to cause a change in
3 turbulence as we've seen by heat kinetic energy changes
4 turbulence.

5 MAGISTRATE JUDGE NOEL: The General Services
6 Administration is incapable of raising or lowering the
7 temperature in this room in any given time frame like that.

8 THE COURT: But they do have a regulation that
9 we're not allowed to use space heaters, so they got that
10 covered.

11 MR. ASSAAD: Well, I'm glad I didn't bring a space
12 heater and turn it off for 1.2 seconds because you would not
13 see any effect in the air flow in this room.

14 It's undisputed that Dr. Abraham did not use
15 particles. This case is about particles. It's not about
16 streamlines. He models streamlines. More importantly and
17 ironically, or very importantly, he destroyed all but one
18 file. He was retained in 2015 during the *Welton* case by 3M
19 by the former attorneys Greenberg Traurig to do a CFD study.
20 He was provided information of CFD studies or data that 3M
21 did as well as testing that was produced. And he had
22 multiples files that were created, and he discussed it
23 during his deposition and even in his published paper he
24 talked about different time steps and different data he had.
25 He admitted that he deleted all the files that plaintiffs

1 would require to reproduce his results.

2 If you look at his expert report, we do not know
3 what equations he used. And, furthermore, he used no people
4 in the operating room. Again, plaintiffs, I don't think
5 anyone here maybe this is the undisputed fact that CFD is a
6 reliable methodology. I think we could all agree on that.

7 Large-eddy simulation which was done by both sides
8 is acceptable. It's transient, it's not a steady state.
9 And the difference between steady state and transient is in
10 transient everything is changing, it's time dependent. You
11 can't turn on the Bair Hugger for 1.2 seconds and say, oh,
12 this is how it is for the next 20 to 30 seconds. Everything
13 is changing. Air moves, particle moves.

14 You saw how long it took for particles to go from
15 the floor to the surgical site. It took over 20 seconds.
16 1.2 seconds is nothing.

17 Plaintiffs' contention is that Abraham's report is
18 lacking in enough description that an individual, an
19 engineer such as Dr. Elgobashi or anyone else in the same
20 field, could have reproduced the report. Or even more
21 importantly, allow myself or anyone else on the plaintiffs
22 to do a vigorous cross-examination, which is what the trial
23 is for, what the jury is for.

24 No dispute that airborne bacteria travels through
25 the air and airborne bacteria travels on skin squames and

1 has a mass and inertia. Elghobashi models squames. Skin
2 squames do not follow streamlines, and it's very important
3 to understand this. Those pretty pictures that you see on
4 Abraham's report with the blue lines and green lines, those
5 are streamlines. Those are you turn on the Bair Hugger for
6 1.2 seconds, you stop it, and you look at what are the
7 velocity vectors of the air at that point in time and you
8 just take a line and draw a line based on the velocity
9 vectors. But the velocity vectors change every single
10 millisecond. Not only that, particles have massive inertia.
11 All experts agree, even Dr. Abraham that skin squames do not
12 follow streamlines.

13 THE COURT: You just don't want to think too much
14 about that, I don't think.

15 Just think how many are in this room.

16 MR. ASSAAD: Streamlines or squames?

17 THE COURT: Squames.

18 MR. ASSAAD: There's billions. This case is about
19 particle movement and turbulent flow. When asked whether or
20 not he was an expert, Dr. Abraham admits he's not an expert
21 in either low speed or high speed turbulent flow. 3M argues
22 that there's a middle speed, but that is -- if you look at
23 3M's response, he doesn't -- 3M doesn't just recite anything
24 regarding his middle speed. There's subsonic flow and
25 supersonic flow. Subsonic flow is anything below the speed

1 of sound, mach one. Supersonic is high speed, over mach
2 one. The fact that Dr. Abraham admits he's not an expert in
3 particle flow in low or high speed, he cannot testify, he's
4 not qualified to testify that he could testify that the
5 particles in the operating room move a certain way or
6 different way after turning the Bair Hugger on in 1.2
7 seconds. He didn't model it. Unlike Elghobashi who was
8 elected to the National Academy of Engineering based on his
9 particle flow and turbulent flow, to understand multistage
10 turbulent flows, the defendants haven't met their burden
11 that Dr. Abraham is qualified to talk about particles.

12 Streamlines assume imaginary particles. There's
13 the word imaginary. There's no such thing as a particle
14 with no mass or no inertia. Particles act differently. And
15 if you compare the videos on Elghobashi, you would see how
16 the velocity of air and particles move in different areas
17 and that's because of turbulence. Turbulence, again, is one
18 of hardest things to measure and calculate and is basically
19 only done by supercomputers.

20 Another thing, sitting here today, plaintiffs have
21 no idea what he modelled. The mesh on his report is a 60
22 million grid mesh. At the deposition, he testified that he
23 based his results on an 8.1 million mesh, and I don't know
24 if this Court recalls what the mesh is from science day, but
25 it's when you take -- when you take the room and you divide

1 it into millions and millions of little squares, okay. So
2 he says his report is 8.1 million, what his results are
3 from. What's pictured in his report is a 60 million grid
4 mesh, and the file -- the one file, that was produced to us,
5 the one file, is a 9.8 million mesh. The importance of the
6 mesh is the accuracy and the calculations involved. This is
7 what he put on his report, a very, very fine mesh, 60
8 million. And he said he ran it and he said it he ran it
9 before science day, but there's no evidence that he did
10 that. This is the mesh that was provided to us on the file.
11 Much different. And it goes to the plaintiffs being able to
12 hire a person to reproduce the results.

13 Now, what's also important is that even this mesh
14 that he provided to us is not the mesh that's on his report.
15 On his report he refers to an 8.1 million mesh for his
16 temperature calculations. We do not have that file. He
17 destroyed all the files except for one.

18 Looking at his report, again, CFD is a reliable
19 methodology if you perform it correctly. If you look at
20 Elghobashi's report, he puts in equations, he puts in
21 exactly what he did, the type of equations, his Duncan
22 conditions, his initial conditions. There's no equations in
23 Dr. Abraham's report. There's no initial conditions. And
24 initial conditions are necessary to reproduce the file
25 results. If I do not know what he starts with, I can't find

1 out what the -- I can't get the results at 1.2 seconds that
2 he did. He has no -- there's no 8.1 million mesh, and he
3 doesn't include the time step. And the time step is very
4 important. The time step is the difference between each
5 calculation of step. So you're a time step of .01, .001.
6 Dr. Elghobashi put that in his report, and he told you when
7 he changed the time step. There was no time step in
8 Dr. Abraham's report. And he admitted during the 40-day
9 run, because he didn't run it on a supercomputer but a
10 laptop, that he changed it multiple times but he doesn't
11 know what it was and what he changed it to. I can't
12 reproduce his results. And when I say I can't, I mean
13 plaintiffs by hiring an expert.

14 Abraham refers to obtaining quasi steady state
15 results to determine that his calculations are correct.
16 First of all, quasi steady state in a transient problem is
17 irrelevant. As you could see from Dr. Elghobashi's video of
18 the particles, it is always changing. It changes. And it
19 takes longer than 1.2 seconds to change. But he admitted
20 that it's impossible for anyone to determine, someone in his
21 field, whether or not his results meet quasi steady state
22 which means there's very little difference without having
23 two data points. We only have one data point at 1.2
24 seconds. He destroyed all the data. We can't reproduce it.

25 He said the only way I could determine whether or

1 not you have a quasi steady solution is to look at two -- at
2 least two TRN files. And TRN files are the data files
3 produced by the ANSYS program. Correct. I only have one
4 TRN file. You understand that, correct? I can't reproduce
5 -- or I can't determine whether or not he had quasi steady
6 state results.

7 And by the way, Dr. Abraham used 106 degrees on
8 his CFD model. I can't reproduce because of a lack of
9 equations, of a lack of initial conditions, and multiple
10 files. The purpose of the expert report is to determine
11 what the expert did. And we produced an expert report where
12 Dr. Abraham came in, was at the deposition of
13 Dr. Elghobashi, and I took his deposition and was able to
14 criticize, as the adversarial process allows to be brought
15 forth in front of a jury. He was able to criticize the
16 equations, his boundary conditions, his mesh, his geometry,
17 his diagrams, that is expert -- that's the adversarial
18 process. The only thing I can -- the plaintiffs could can
19 at trial is to say you didn't put down your equation, you
20 didn't give us a time step, and we couldn't reproduce your
21 report. I can't run his report or run his data and say this
22 is what's going to happen.

23 Abraham even agrees to reproduce the results in
24 these initial conditions, the time step, the mesh, and the
25 geometry. We don't have any one of them. We don't initial

1 conditions, the time step. The mesh that he used is not the
2 one that he provided to us. And by the way, the mesh that
3 was provided to us, the TRN file, was not in response to the
4 expert report. It was provided to us when we subpoenaed
5 Dr. Abraham when he published the CFD on 3M's website and 3M
6 agreed that it was no longer confidential and they give us
7 one TRN file many, many months before the expert reports
8 were due.

9 THE COURT: Okay. So I think you pretty well
10 covered that his work is not reproducible, and I guess you
11 say it doesn't make any sense. Okay. Go to your next slide
12 then.

13 MR. ASSAAD: This is the fog experiment that he
14 did afterwards saying that he tested his results. Again,
15 first of all, I showed you what validation looks like. It's
16 a graph. It's not just I went and took a couple
17 temperatures around the room. Especially when you run the
18 Bair Hugger for 1.2 seconds, you're not going to see a
19 temperature difference anywhere in the room. And he didn't
20 identify where he took temperatures.

21 He also states that the model shows that the Bair
22 Hugger forced-air warming does not add appreciably to the
23 cooling work of the operating room. If this model of 1.2
24 seconds change the operating from 59 degrees to 62 degrees,
25 that is almost like an atomic bomb blowing up an operating

1 room because I don't think any heater could heat this room
2 in 1.2 by three degrees. I can't reproduce or
3 cross-examine. He didn't provide the video for the full
4 visualization. He didn't provide the data. He didn't
5 provide pictures. Ipse dixit, I did it, I validated it, it
6 was correct, I'm not going to provide any underlying data.
7 And if you look at his report, there's one paragraph on his
8 testing with no underlying data, no videos. Of course 3M
9 says you could look at the videos online. That's not part
10 of his report. That has not been submitted into evidence.
11 That's --

12 THE COURT: Okay. I think we have a good sense
13 for why you think Abraham ought to be excluded. Let me hear
14 from the defense. And then if there's something that you
15 need to respond on, we'd be happy to hear from you.
16 Mr. Goss.

17 MR. GOSS: Thank you, Your Honor. I'll be -

18 THE COURT: It sounds bad that the files were
19 destroyed and the information can't be reproduced.

20 MR. GOSS: All right, it sounds bad but it isn't.
21 We reproduced the master file for the entire CFD in response
22 to subpoena last November. I was at Dr. Abraham's
23 deposition. They had the CFD. Mr. Assad was manipulating
24 it in front of our very eyes and asking Mr. Abraham --
25 Dr. Abraham lots of questions about it. When it came our

1 turn with Dr. Elghobashi, we were provided a file that was
2 proprietary. We couldn't even play it because we didn't
3 have the software. So for him to suggest that somehow he
4 didn't have the information he needed to do the deposition,
5 which went a full -- went well over seven hours is just not
6 true. We haven't heard anything from Dr. Elghobashi that
7 there was anything missing from Dr. Abraham's report that
8 would not allow him to be able to understand the work that
9 was done and to reproduce it if he chose to do so. All
10 we've heard is complaining from lawyers but nothing from
11 Dr. Elghobashi. At his deposition he didn't say a word
12 about Dr. Abraham not producing things. So this is really
13 all lawyer argument is what it is.

14 THE COURT: But destroying the files.

15 MR. GOSS: He didn't --

16 THE COURT: That's not something somebody would
17 make up.

18 MR. GOSS: Well, he just didn't retain them. He
19 kept the master files, but he's got a lot of computer files
20 over there at St. Thomas. It's not -- he didn't destroy.
21 He just didn't maintain them. They were culled in the
22 normal process of the way any of us, kind of like you have
23 files, after you finish working on something, the drafts
24 aren't retained. That's really all it is. So there was no
25 deliberate destruction. And again, we produced the master

1 file back in November. We didn't hear a peep from the
2 plaintiffs about this isn't enough, we don't understand it,
3 it's not enough detail until Dr. Elghobashi's deposition, at
4 which point he is cross-examined to the Nth degree about
5 every last little thing he may have done to prepare his
6 opinions in this case. So there was no deliberate
7 destruction. The master file was produced.

8 MAGISTRATE NOEL: Did he use 106 degrees as the
9 temperature under the blanket -- or under the drapes?

10 MR. GOSS: Yes, but, again, his model is very
11 different from Dr. Elghobashi's. It comes out of the head
12 and neck and at a lower velocity. If he were here, he could
13 explain it lot better than I can, which goes to show that a
14 lot of these criticisms are really about weight and not
15 admissibility on Dr. Abraham's side.

16 As to the complaint about modelling air instead of
17 particles, again, I'm not an engineer. Mr. Assad would be
18 quick to remind you that I'm not an engineer. But if the
19 air doesn't get there, then how do the particles get there?
20 Their whole theory is disruption of air flow and if the air
21 delivers particles to the surgical site. Well, if the
22 streamlines aren't getting there, that means that the
23 particles can't get there either because they will drop out
24 because of inertia and their own mass, according to what
25 Mr. Assaad just said.

1 So that's really all I had to say in response to
2 the motion, unless the Court has any other questions.

3 THE COURT: Nope. Thank you.

4 MR. GOSS: Thank you.

5 MR. ASSAAD: Could I have one minute, Your Honor.

6 THE COURT: Yes.

7 MR. ASSAAD: Dr. Abraham did not produce a master
8 file. Every time you run a CFD and you get a result for
9 every time step, it spits out a file. So if you run it with
10 a .1 time step, when that time step is solved, it spits out
11 a data file. So he didn't produce the master data file, and
12 it's clear there's more than one data file, and that's how
13 you determine whether or not you get quasi steady state by
14 comparing one data file to the second. In his deposition on
15 page 53, I asked, So those files have been destroyed? Well,
16 I mean, there's no reason to keep them. He destroyed those
17 files. He deleted them. He deleted our ability to perform
18 a vigorous cross-examination and run his file. He admits
19 that we can't replicate what he does.

20 MAGISTRATE JUDGE NOEL: I guess I'm confused by
21 just listening to the lawyers because Mr. Goss just told us
22 that at the deposition you did reproduce it, you ran through
23 several iterations of what it was and made changes and said
24 do this, do this and he did it. What is it that you can't
25 do?

1 MR. ASSAAD: Let me explain. So every time you
2 run a -- every time the CFD comes up with a result, it
3 creates a data file. And in that data file, you could see
4 what the temperature grading is, what the streamlines are,
5 and what occurred. I have the data file only for 1.2
6 seconds, okay. He said that he ran the data for -- I have
7 -- let me rephrase it. I have data file number 264. And
8 every time you run, it gets a result, you got 265, 266, 267.
9 He deleted 1 which initial -- his initial conditions to 263.
10 Only 264 was reproduced. He said he ran up to 2500 or 3000
11 time steps, whether or not you want to believe his
12 deposition or his published paper that's not part of the
13 evidence. And I don't have any of those. Those were
14 requested, those were relied upon, and they've been deleted
15 and he said he deleted it.

16 Without those two information, first of all, I
17 can't determine whether or not that he got correct results
18 or proper results. I can't determine quasi study to say the
19 difference between this time step and that time step is so
20 small that I'm almost at study state which Dr. Abraham
21 admits I can't do. And without the initial conditions of
22 what you started with, what data you put in, I cannot
23 reproduce. And under Daubert, you should be able to have
24 enough sufficient information for someone in the field to
25 reproduce the results. And yes, I had one file and I could

1 see the mesh. I showed you the mesh which -- I showed the
2 mesh that were provided to us is not the same mesh that's in
3 the report and different than the mesh that he testified to.
4 We're not even sure that the file he gave us is the file
5 that created those pictures and his report because the
6 meshes don't match up. That's all I have, Your Honor.

7 THE COURT: All right. Who is the making the
8 motion -- who is speaking to the motion about Ho?

9 MR. BANKSTON: Me, Your Honor, Mark Bankston.

10 THE COURT: All right. I'm sorry?

11 MR. BANKSTON: Mark Bankston on behalf of all
12 plaintiffs to argue the motion to exclude Dr. Ho. Your
13 Honor, I'm going to keep us moving fast. No prelude, let's
14 just talk about Dr. Ho. Dr. Ho is a little bit of unusual
15 expert. He's a late addition, hired substantially later
16 than all of the rest of our experts. He's about two weeks
17 before his report, and then he produced a report.

18 Dr. Ho is a gentleman who works for the Canadian
19 Military. His career has been spent developing devices that
20 perform optical laser and other types of sampling of
21 bacterial particles and biological aerosols. He did not do
22 any of that in this case, though. The only thing he has
23 done in this case is write a report based upon some
24 materials that he's collected.

25 There are two primary reasons that we seek his

1 exclusion, the first being that the number one point that
2 Dr. Ho is meant to address is this thing that we've been
3 talking about for a long time which is whether airborne
4 particle matter can act as a reasonable surrogate for the
5 presence of bioburden in the air. As you know, it's a
6 hugely contested thing between the parties, and we've heard
7 a lot of studies about that, both from their side and from
8 our side. Dr. Ho gave an opinion on that matter but
9 reviewed virtually none of those studies. Argument is not
10 that every expert has to review every relevant piece of data
11 in the field or every relevant piece of scientific
12 literature, but an expert cannot just abjectly ignore and
13 fail to review the great bulk of all of the literature
14 that's out on this subject and then come in and give an ipse
15 dixit opinion on what that is.

16 I just want to briefly go through what those
17 studies are. Of course you've heard a lot about Darouiche.
18 Dr. Ho did not review Darouiche. He was shown it during
19 deposition. He immediately concluded it must have been
20 wrong. He said Dr. Darouiche must be motivated in some way
21 would to manipulate the results. It came out he obviously
22 has a bias. In their response, 3M has a lot of criticisms
23 of Darouiche. None of those come from Dr. Ho because, of
24 course, Dr. Ho never even read Darouiche when coming to his
25 opinions. Obviously when we have somebody up on the stand

1 talking about Darouiche or particles and proxies, they're
2 going to have a very aggressive cross-examination, but none
3 of that comes from Dr. Ho.

4 One article that hasn't been talked about a lot
5 today or yesterday as well is the article by Reval, et al.
6 And this was published in *Cytotherapy* I believe 2014, I may
7 need to check on that date. There was also another one
8 that's cited in our papers that Dr. Ho did not review. He
9 also quickly reviewed that and quickly determined it was
10 wrong in the midst of a deposition after two or three
11 minutes of looking at it. There is another paper by Wing,
12 et al., also concluding that particle mass is a reasonable
13 representation for airborne particles, did not review that
14 either.

15 He did review the paper by Stocks. That's one of
16 the ones he did that is mentioned in his report. This is a
17 paper that he said that upon immediate glance at the data,
18 just looking at Figure 1, instantly any qualified person
19 would be able to tell the study is junk, this is the one
20 that's discussed in our papers, though, where when the study
21 came out, 3M sent it to Russ Olmsted at the National
22 Institute of Health who they retained as their biological
23 specialist who does microbiological testing and sampling.
24 He's the one who described the Stock study as fairly
25 remarkable study, particularly for the ability to be present

1 during the actual procedures, and said that it does stand
2 for the proposition and is a reasonable finding that
3 bacteria acts as bioburden. It really has Mr. Ho has --
4 Dr. Ho has no solid explanation of why to dismiss this study
5 except that any qualified person who sees it would
6 immediately discount it. That's clearly not true. That is
7 one of the few studies he actually did review.

8 The only other study that really is meaningful to
9 his opinions that he did review is this older study by Seal
10 and Clark that's also another one that supports bioburden as
11 proxy by particulate matters. I'm just going to quote for
12 you what he said about it. He did review this one and said,
13 speculatively, if the dataset from panel 2D was compared to
14 ultraclean live particles, it would appear unlikely to relay
15 positive, significant experiment correlation. So at least
16 on this one study, there was some semblance of something
17 that looked like analysis, but even by Dr. Ho's own
18 admission, it's completely speculative. He's only
19 discounting the regard of the study by making his own
20 independent speculations about the data. He's not done any
21 actual analysis of it.

22 All of these studies, this large body of
23 literature where he's only reviewed a couple of these
24 studies, are things that he wants to testify about now
25 despite not having had any opinions about them in his

1 report.

2 If you look on the other side, which is what does
3 he have to support the opinion that there is -- I mean, in
4 other words, why was he able to ignore this large consensus
5 body of literature? And if you look at 3M's response, they
6 start citing different studies about why Dr. Ho should be
7 able to ignore this literature. They say he was -- they
8 discuss and say Bergan in 2015. Dr. Ho did not review the
9 Bergan study. It's not included in his report. He did not
10 base any of his opinions on it.

11 They also cite a literature review by Mora, et
12 al., which does talks about some of the studies that we've
13 been talking about. Dr. Ho did not review that study. It
14 does not form any part of his opinions.

15 They talked a little bit about a study called
16 Landrin is one of the ones he cited that actually is in his
17 report. Landrin is actually discussed by many of the other
18 studies, the significant limitations of that study and the
19 aberrant results. In fact, the aberrant results of Landrin
20 are, in fact, the motivating factor why so many studies have
21 been done since then.

22 None of those limitations are discussed by Dr. Ho,
23 even though he read the Stock study, he read Darouiche, he
24 knows those limitations exist. None of that was addressed.
25 That's the only thing that's in his report that really

1 supports any of this because the only other thing you could
2 even remotely site is a study by Christina, et al., which
3 discussed 3M's paper. The problem with that study is they
4 measured particles in that study from the release of smoke
5 from electrosurgical tools. And, in fact, they were only
6 measuring two different particle sizes which are directly
7 associated with smoke released from electrosurgical tools.
8 The author specifically discussed this limitation and, in
9 fact, said they warned the study cannot be used to
10 contradict a correlation between the number of particles per
11 meter cubed and CFUs per meter cubed which they noted was
12 reported by the Stocks paper. So the very purpose why 3M
13 was hoping to use this paper is disclaimed by the authors,
14 do not use this to try to contradict Stocks.

15 So at the end of the day, Dr. Ho has virtually no
16 support. The only thing that you could even begin to pin on
17 it was Landrin, and so you have this one outlying study that
18 has been roundly rejected by the rest of the literature, and
19 the rest of the literature he didn't even review.

20 When an expert so abjectly fails to acquaint
21 himself on the body of literature, we don't believe that
22 that's a reliable methodology because there's nothing else
23 in his training, background, experience in which he's
24 published any studies like this or done any sort of work
25 like this. It appears that at the very last moment, in the

1 hope to fight this issue, 3M retained a person, gave him a
2 couple studies but he did not have the time or ability to
3 fully acquaint himself with the materials. For that reason,
4 on that topic, we believe he should be excluded.

5 THE COURT: Okay.

6 MR. BANKSTON: There's just one other really quick
7 thing.

8 THE COURT: Okay.

9 MR. BANKSTON: And that is, he gave a filter
10 opinion. He says the filter but didn't admit it in
11 deposition. The only opinion he can give is that it's
12 reasonable for the mechanical operation of the device,
13 specifically disclaimed in the ability to talk about its
14 safety, and that's something else I think you should see in
15 the papers.

16 The only other thing in the papers that I think is
17 really worth looking at is this was one of the most unusual
18 witnesses I've ever taken a deposition. His degree of
19 advocacy, the ability in which he would so radically depart
20 from how a reasonable person would answer is striking. And
21 I don't want to go into too much about that because I think
22 it's really something you need to read on the paper in the
23 papers. And when you see it, it is -- it was really
24 disturbing to me to see how much this expert, and it's not
25 totally his fault, he's a neophyte, he doesn't understand --

1 he's not a regular testifier, but he flat out admitted that
2 he believes his role was to be advocate for 3M and to
3 criticize stuff that is unfavorable to 3M but not to
4 criticize things that are favorable to 3M.

5 THE COURT: All right.

6 MR. BANKSTON: Let's -- for all those reasons we'd
7 ask --

8 THE COURT: All right. Thank you, Mr. Bankston.

9 Who's going to stand up and speak to Dr. Ho?

10 MR. GORDON: That would be me, Your Honor. I'll
11 be very brief. We haven't talked much about it, but I want
12 to just bring up the fact that there's a different standard
13 that applies to rebuttal experts. Dr. Ho is a rebuttal
14 expert. We didn't hire him to come forth with opinions to
15 meet our burden of proof; rather, we hired him to address a
16 couple of very specific issues that go to what the
17 plaintiffs are relying on. Dr. Ho is a microbiologist.
18 He's the only microbiologist on either side. He's not just
19 a microbiologist. His speciality is aerobiology. He's not
20 just an aero biologist. He may be the world's leading
21 expert on the determination -- on realtime assessment of
22 viable pathogens that are airborne.

23 The reason for -- and let me explain that very
24 briefly. He has spent his career developing a system, a way
25 of doing realtime measurements of biohazards that are

1 airborne, initially for the Canadian Military, it's now been
2 shared with and he works with the U.S. military and, in
3 fact, all NATO forces use and rely on his equipment. Why?
4 For chemical warfare. When the NATO forces are out in the
5 field and there's a concern that, you know, some enemy
6 forces might deploy chemical weapons, they need something
7 that can tell them right now in realtime, let's put on our
8 gas mask.

9 Now, based on plaintiffs' theory, all they'd have
10 to do is use a handy particle counter and, you know, since
11 particles equals bacteria, you know, that's all they need to
12 do. That's so patently silly to tell, you know, to say that
13 the military should just rely on particle counts as a
14 surrogate. They don't rely on it as a surrogate for very
15 good reason. It's no surrogate. Particles are a quick and
16 dirty way of assessing in realtime, you know, potentially
17 where contaminants might be. If you want to -- you can't do
18 real -- well, without Dr. Ho's equipment, you can't do
19 realtime measurements of actual bacteria. You can do very
20 quick realtime assessment of particles. So if you're in an
21 OR and you want to get a sense of what's going on, you can
22 do a quick particle measurement. If it's really low, that's
23 probably a good indication that it's a pretty clean
24 environment. If it's really high, maybe you got a concern,
25 you got to do bacteriological sampling to know, but

1 plaintiffs whole case, a major component of it, is syllogism
2 that particles equals bacteria, Bair Hugger emits particles,
3 therefore Bair Hugger must be admitting particles. You've
4 always got to be careful of syllogisms for all matter will
5 be Socrates.

6 But let me see if I can give you a different
7 comparison. We know that most of the lakes in Minnesota
8 have fish in them, lots of fish, some more than others.

9 But there are probably some lakes that have
10 absolutely no fish. And if you know that a lake has no
11 fish, you've measured it, you've done nine tests of it,
12 you've determined that there are no fish in a lake, the fact
13 that you could say -- and, generally speaking, lakes
14 correlate with fish, with fish being in them, that doesn't
15 mean that there must be fish in the lake that you already
16 know there aren't any fish in.

17 MAGISTRATE JUDGE NOEL: Just to follow that
18 syllogism, 3M has no scientists who say that there is no
19 bacteria, correct? In other words, nobody has studied this
20 bacteria issue? That's the whole point, I thought.

21 MR. GORDON: Actually, there have been nine -- we
22 could go over them, but there have been nine published
23 studies where a number of different researchers, including
24 most recently the Oguz paper, we've talk about that at
25 length, have in fact studied is there a connection between

1 the use of the Bair Hugger and the increased bacteria. And
2 there's a reason -- and so there are nine published studies,
3 and there are seven secret studies done by Augustine and his
4 colleagues. There is a rich body of scientific literature
5 that demonstrates that whatever the general proposition for
6 particles might, under certain circumstances, equal
7 bacteria, that's not the case with the Bair Hugger. And
8 that's not incredible. That's one of the areas where Dr. Ho
9 can provide insight to the jury. The Bair Hugger is a warm,
10 dry environment. That is not a happy place for bacteria.
11 So the idea that air coming out of the Bair Hugger might not
12 actually contain viable bacteria, even though it might
13 contain lots of tiny little particles, that makes perfect
14 sense, microbiological sense. And Dr. Ho as a
15 microbiologist, whose life's work has been dedicated to
16 determining the bio burden of actual -- actual viable
17 things, is in a perfect position based on his own
18 experience. Yes, he did read the key research. The
19 plaintiffs rely heavily on the Stocks paper. He reviewed
20 that. He critiques it. They don't like his critique of it.
21 That's fine, but -- and they showed him a couple of other
22 papers that he hadn't seen, one including literally a
23 chicken coop where they measured the bacterial burden in the
24 air on the chicken coop and correlated with the particles.

25 Right after 9/11, when there was the apparent

1 anthrax attacks in D.C., the CDC sent a plane up to Medicine
2 Hat, Alberta, to get Dr. Ho and his equipment and his team
3 to fly to Washington to measure the post offices and the
4 Senate offices for the SARS virus. When a Toronto hospital
5 was dealing -- I say SARS. With anthrax. When a Toronto
6 hospital was dealing with a SARS outbreak, they brought in
7 Dr. Ho to use his --

8 So plaintiffs criticize our experts if they've
9 done only a literature review. Now they criticize Ho for
10 not doing what they think is a thorough literature review.
11 He reviewed plenty of literature, but he is an expert, the
12 expert, if you will, in aerobiology and is perfectly
13 situated as a rebuttal expert to critique the plaintiffs'
14 syllogism and their theories.

15 He's also able to explain to the jury how bacteria
16 behave in the air, the size of the bacteria, how they tend
17 to clump and travel in packs and travel on fomites, they
18 don't travel as tiny little particles, and to quantify the
19 size and therefore allow others to put the pieces together.

20 But he is certainly qualified, even if he didn't
21 read anyone else's paper, but he did read the relevant
22 studies. And he is critiquing. He is critiquing this
23 syllogism upon which plaintiffs so heavily rely and for
24 which there is no scientific support as applied to the Bair
25 Hugger. And, in fact, there is ample scientific, robust

1 scientific report uniformly rejecting the notion that the
2 Bair Hugger, whatever particulate increase occurs from the
3 Bair Hugger, the evidence is clear it is not viable
4 bacteria.

5 And with that, I'll rest on the papers.

6 THE COURT: Okay. Thank you, Mr. Gordon.

7 MR. GORDON: Thank you.

8 THE COURT: I believe we have to recess today
9 again at 4:30.

10 Mr. BANKSTON: Let's keep things moving then. I
11 don't need any extra time.

12 THE COURT: Okay. But I think we might be able to
13 cover Lampotang.

14 MR. FARRAR: We can, Your Honor. My name is Kyle
15 Farrar. I haven't been able to speak the last couple days,
16 so just so you know my name.

17 We're mostly going to rely on the papers on
18 Dr. Lampotang, but just a quick background. He's an
19 engineer and not a doctor, but he is Dr. Lampotang.

20 The real criticism is his methodology or complete
21 lack thereof. He testified specifically that he didn't use
22 the same methodology he would were he in an academic
23 setting. And he says on page 248 of his deposition, "I was
24 not writing a paper in my mind, so I didn't apply the same
25 approach that I would use for an academic paper."

1 And if we look at his report and his deposition,
2 it becomes clear -- and I would implore the judges to really
3 look at his report as opposed to listening to me talk about
4 it, but if you look at the materials considered, he's got a
5 handful of plaintiffs' experts' reports, a handful of
6 depositions, cherry-picked documents and eleven pieces of
7 literature, none of which are the nine pieces of literature
8 that 3M has been flashing up that they claim to show that
9 there is no association of causation with the Bair Hugger
10 infection rates. And then he comes to some conclusions that
11 are kind of just the overall arching conclusions of the
12 case, like the Bair Hugger warming unit is safe, Arizant and
13 3M acted reasonably in designing, developing and marketing
14 the Bair Hugger. There's no methodology behind it. This is
15 that ipse dixit, which I never can say right. He's just
16 saying it. He said, look, I looked at this stuff and these
17 are the conclusions. There's no tie to it. He says
18 specifically 3M acted within industry standards in the
19 design, testing, evaluation and development of the Bair
20 Hugger. He doesn't tell us what the industry standards are.
21 Where is he gathering that information? What is he looking
22 at to make that determination? He has an interesting
23 opinion where he says it is my opinion that Arizant and 3M
24 took the high road and acted with poise and restraint in its
25 official response to allegations about his forced-air

1 warming technology. I don't know if he's a warming expert
2 or a human factors expert or a marketing expert, but that's
3 just not an opinion that's relevant to the case. But, more
4 fundamentally, where is he getting it from? What's the
5 methodology that he comes up with any of his opinions? So
6 that's really the criticism. If you look through his
7 report, he's got eleven different opinions, none of them
8 does he give an actual methodology of where he came up with
9 them, and he certainly didn't review the materials that
10 would be necessary to come up with these kind of overarching
11 huge conclusions.

12 Thank you, Your Honor.

13 THE COURT: Thank you, Mr. Farrar.

14 Ms. Lewis.

15 MS. LEWIS: Good afternoon.

16 I am just sort of taken aback, because I think
17 that's the weakest argument that plaintiffs can make with
18 respect to Dr. Lampotang, that he did not follow how you
19 would follow writing an academic paper. As he mentioned in
20 his deposition, he's not writing an academic paper. He's
21 writing an expert report. And he did not -- you know, he's
22 not an expert testifier, so he may not know everything that
23 he is supposed to write on his materials-considered list.
24 Those were some of the questions that he was asked during
25 his deposition.

1 The other thing that happened during his
2 deposition is plaintiffs refused to show him things he asked
3 to see. They would ask him, "Have you seen this particular
4 document?" And he said, "I don't know. Show me the
5 document, so I can see if I've reviewed it." And they
6 wouldn't show it to him. So that was several times
7 throughout his deposition. Have you seen this document? I
8 don't know; can you show me the document, so I can say?
9 There have been lots, hundreds, thousands of documents
10 produced, so -- and they're basing their argument on the
11 fact that they didn't have the courtesy to show him
12 documents so that he could say yes or no, "I've reviewed
13 them." But let me talk about his methodology.

14 As he mentions in his report, he reviewed the
15 510(k) design history file for both model Bair Hugger units.
16 He reviewed the 510(k) submission to the FDA on the Bair
17 Hugger. He reviewed filter efficiency testing concerning
18 the Bair Hugger filter. These were things he was going to
19 talk about. He reviewed and looked at the ASHRAE standards,
20 what do the ASHRAE standards require? We've already talked
21 about the fact that the FDA does not require a filter for
22 the Bair Hugger system, but he looked at what did the ASHRAE
23 standards contain, because, as we've talked about earlier,
24 the Bair Hugger filter is a MERV14 filter. So he wanted to
25 look to see what MERV14 talked about. So he looked as those

1 standards. He looked at the testimony of the corporate
2 representative of the vendor that supplied the filter
3 material to 3M. He looked at the exhibits to that
4 deposition, and he reviewed that deposition testimony.
5 Those are just some of the things he did.

6 With respect to the literature, Dr. Lampotang goes
7 into very detail about his review of two studies, the Avidan
8 study that we've talked about, which was, again, placing the
9 hose over the petri dish, getting bacteria, but when you
10 apply the blanket you got zero. So that gave him some
11 information about the Bair Hugger in its intended use in the
12 OR.

13 He also looked at a Bernards study. Plaintiffs
14 haven't talked about it too much. I take that back. Maybe
15 they did. Maybe Ms. Conlin did. Yes, she did. She said
16 there was dust removed from the Bair Hugger filter. And
17 Dr. Lampotang goes through great detail describing in his
18 report that that's not what the study says. So the study is
19 an exhibit. I was hoping to be able to give it to you. I
20 think it's attached to my declaration in opposition to
21 plaintiffs' motion to exclude. But he goes into detail. So
22 he reviewed what he needed to review to answer the questions
23 that he was going to address, which was, Was there an issue
24 with the filter, Was there an issue with other things about
25 the design. That's why he looked at the design history

1 file.

2 He knows about the studies that plaintiffs talk
3 about. He talked about them in his report. So that's also
4 included in his report.

5 He also talked about some of the criticisms that
6 he had about plaintiffs' experts. They talked about a study
7 by a man named Moon in Houston that had to do with soot.
8 And so I won't go into detail here, but just to say that
9 Dr. Lampotang looked at that study, offered his opinion on
10 why that had nothing to do with whether bacteria would come
11 out of the Bair Hugger when in use.

12 So his methodology was appropriate. He relied on
13 scientifically reliable and valid studies. He came up with
14 his opinions based on his review of those studies. As is
15 evident from his qualifications, he's an inventor, he's a
16 researcher. He knows about thermal dynamics. He deals with
17 heat conduction. He knows about that. He's done research.
18 He's a principal investigator on those issues. So he knows
19 what to do with respect to the criticism about, you know,
20 does he know what the industry standards are. I don't know
21 that they asked him that question. They could have asked
22 him that question, what are the industry standards on which
23 you are relying, but they didn't. But because he is an
24 inventor, a researcher involved in medical devices, you
25 know, he could have answered that question, but that would

1 be, again, what he would base his opinions on partly because
2 of his experience, 35 years of experience as a researcher,
3 and especially with respect to medical devices.

4 I think beyond saying that, we'll probably rest on
5 our papers.

6 THE COURT: Very well. Thank you, Ms. Lewis.

7 We will tomorrow talk about David and Ulatowski.

8 Ms. Conlin, you have a thought?

9 MS. CONLIN: Well, Your Honor, I had the citations
10 that you requested from McGovern authors, but I'm happy to
11 pick up with that in the morning, if you would like.

12 MAGISTRATE NOEL: Are they just quick things that
13 we can do in 30 seconds?

14 MS. CONLIN: I can do it in probably 45, Your
15 Honor.

16 MAGISTRATE NOEL: Okay.

17 MS. CONLIN: The first citation is in Docket 910.
18 Exhibit 16. It's out of Dr. McGovern's testimony.
19 Line 415 -- or internal page 415, lines 8 through 20, as
20 well as internal pages 375, 9 through 14.

21 There's also Professor Nachtsheim's testimony.
22 Docket No. 910. Exhibit 12 -- I'm sorry -- yeah, Exhibit 12
23 at page 12, internal page 350, lines 4 through 8. "You
24 continue to stand by the results of the observational data
25 in McGovern?" Answer, "I do."

1 We also found Dr. Reed's testimony. Docket No.
2 751. Exhibit 1 at 311. That was Mr. Hulse's declaration,
3 so it was testimony that went in in 3M's submission.
4 Internal page 226, lines 12 through 20.

5 The question to Dr. Reed, "Do you stand by your
6 studies, correct?"

7 Answer, "Yes."

8 "And even though Mr. Albrecht and Dr. Augustine
9 funded some of the studies involved, they did not influence
10 the data or results that you have concluded, correct?"

11 Answer, "Yes. So just to be clear, there was no
12 funding of any of these studies apart from the very first
13 one, which was the one actually that didn't show any
14 deference, but, yes, I do stand by them, yes."

15 I also, Your Honor, you asked about whether there
16 was specific testimony related to an association, that the
17 author said is an association. Because we didn't know that
18 there was an issue on that, we didn't submit those, but we
19 do have -- and I've got citations; I can file them with the
20 court -- where the authors go through and say, for example,
21 Mr. Albrecht says, answer, "I would agree that it's
22 associated with the 3.8 times increase. That's what the
23 study would say." So I was able to find it in various
24 places in the testimony. If you want me to submit them as
25 supplemental exhibits, I will, but, to be honest with you,

1 Your Honor, even Mr. Gordon said yeah, the McGovern study
2 shows an association. We didn't, until the questions by
3 Your Honor, understand that that was an issue or holding you
4 up on that. I mean, what the authors say --

5 THE COURT: This just started because early
6 yesterday the argument was "All we have to have is
7 association" and then we go to the Bradford Hill, so
8 that's --

9 MS. CONLIN: Absolutely. And to be clear --

10 THE COURT: And so don't submit anything new
11 without running it by Mr. Blackwell and company.

12 MS. CONLIN: Okay. And just to be clear, Your
13 Honor, they say that the McGovern study shows association,
14 not causation, consistent with what we've represented to the
15 Court.

16 THE COURT: Tomorrow we will resume at 9:30,
17 rather than 9 clock. Have a good evening. We're in recess.

18 MAGISTRATE JUDGE NOEL: Is Mr. Gordon going to be
19 here tomorrow?

20 MR. GORDON: Yes, sir.

21 MAGISTRATE JUDGE NOEL: Okay. I have a question
22 on those nine studies, but I'm going to save it for
23 tomorrow.

24 (Court adjourned at 4:30 p.m.)

25 * * *

1 I, Maria Weinbeck, certify that the foregoing is a
2 correct transcript from the record of proceedings in the
3 above-entitled matter.

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5 Certified by: /s/Maria Weinbeck
6 Maria Weinbeck, RMR-FCRR
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